Collaborative Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

Subproject:

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

Executive Summary/Abstract

Die DZIF TTU HIV plant eine deutschland-weite Kohorte an Patienten aufzubauen, die sich in der akuten HIV-Infektion vorstellen. In vorgelegtem Projekt soll hierfür eine Pilotsutdie durchgeführt werden. Alle Voraussetzungen für die Patientenrekrutierung werden geschaffen werden. Am Ende der Förderperiode werden die ersten Patienten eingeschlossen. Die Patienten werden gesammelt, um zunächst Korrelate der Immunantwort in der akuten HIV-Infektion zu bestimmen – entweder mit oder ohne antiretrovirale Therapie. Später soll die Kohorte jedoch auch für Interventionsstudien Verwendung finden. Aufgebaut wird die Kohorte in enger Kollaboration mit Prof. Dr. G. Behrens und seiner Arbeitsgruppe.

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

Die DZIF TTU HIV plant eine deutschland-weite Kohorte an Patienten aufzubauen, die sich in der akuten HIV-Infektion vorstellen. In vorgelegtem Projekt soll hierfür eine Pilotsutdie durchgeführt werden. Alle Voraussetzungen für die Patientenrekrutierung werden geschaffen werden. Am Ende der Förderperiode werden die ersten Patienten eingeschlossen. Die Patienten werden gesammelt, um zunächst Korrelate der Immunantwort in der akuten HIV-Infektion zu bestimmen – entweder mit oder ohne antiretrovirale Therapie. Später soll die Kohorte jedoch auch für Interventionsstudien Verwendung finden. Aufgebaut wird die Kohorte in enger Kollaboration mit Prof. Dr. G. Behrens und seiner Arbeitsgruppe.

Chapter 1: Description of the task

a) Tasks/objectives

The aim of this proposal is to start a pilot cohort in collaboration with Prof. Behrens, Hannover, in order to establish the IRB approval and the network necessary for the following nation-wide cohort.

Capacity building objectives

1. Enroll Munich patients into a retrospective cohort of patients diagnosed during acute HIV-1 infection (TopHIVpast) (Draenert)

2. Enroll patients in Munich prospectively for a joint cohort of patients diagnosed in acute HIV-1 infection (TopHIVfuture) (Draenert)

Project objectives

- Prepare study protocol, IRB application and patient consent form
- Collect clinical data on TopHIVpast cohort in collaboration with the team led by Prof. Behrens
- Start enrolling patients in the TopHIVfuture cohort

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

The aim of this proposal is to start a pilot cohort in collaboration with Prof. Behrens, Hannover, in order to establish the IRB approval and the network necessary for the following nation-wide cohort.

Capacity building objectives

1. Enroll Munich patients into a retrospective cohort of patients diagnosed during acute HIV-1 infection (TopHIVpast) (Draenert)

2. Enroll patients in Munich prospectively for a joint cohort of patients diagnosed in acute HIV-1 infection (TopHIVfuture) (Draenert)

Project objectives

- Prepare study protocol, IRB application and patient consent form
- Collect clinical data on TopHIVpast cohort in collaboration with the team led by Prof. Behrens
- Start enrolling patients in the TopHIVfuture cohort

b) Prerequisites

The DZIF HIV TTU has started to establish a national multi-center, early HIV infection cohort (responsible: Prof. Behrens) to support studies within the Topic “HIV Cure & long term remission”, including effects of early HAART intervention, dynamics of HIV integration sites, HIV cell reservoirs and development of immune responses among others. The long-term objective will be to identify correlates of HIV Cure & long-term remission and test novel therapeutic intervention strategies. The multi-center cohort study design is necessary, because detection of acute/early HIV cases is expected to be infrequent at individual DZIF partner sites (ref French cohort). However, it requires a high degree of harmonization between the participating sites. Different lab procedures will be performed at different HIV TTU Institutions and require a functioning collaborative and national network.

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

The DZIF HIV TTU has started to establish a national multi-center, early HIV infection cohort (responsible: Prof. Behrens) to support studies within the Topic “HIV Cure & long term remission”, including effects of early HAART intervention, dynamics of HIV integration sites, HIV cell reservoirs and development of immune responses among others. The long-term objective will be to identify correlates of HIV Cure & long-term remission and test novel therapeutic intervention strategies. The multi-center cohort study design is necessary, because detection of acute/early HIV cases is expected to be infrequent at individual DZIF partner sites (ref French cohort). However, it requires a high degree of harmonization between the participating sites. Different lab procedures will be performed at different HIV TTU Institutions and require a functioning collaborative and national network.

c) Planning of the project

The project was mainly planned by Prof. Dr. med. Georg Behrens at the MHH in Hannover. This report covers the coordinating site in Munich. Therefore Munich plans the study at the LMU Munich as well as the external Munich sites, namely the private practice including:

Design of study protocol

Approval by IRB committee

Organisation of study within Munich - meetings with external partners (=private practices)

Organisation of patient recruitment

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

The project was mainly planned by Prof. Dr. med. Georg Behrens at the MHH in Hannover. We are the coordinating site in Munich. Therefore we plan the study at the LMU Munich as well as the external Munich sites, namely the private practice including:

Design of study protocol

Approval by IRB committee

Organisation of study within Munich - meetings with external partners (=private practices)

Organisation of patient recruitment

d) Scientific and technical status built on

The goal of this pilot grant is to initiate the cohorts required for a national multi-center primary HIV infection cohort. Munich partners will establish the requirements with regard to ethical approval, collaboration with external Munich sites (e.g. private practices) and patient recruitment. Importantly, this project is planned to turn into one part of the multi-center cohort.

1. Ethical approval:

Study protocol, patient consent form and IRB application will be prepared in accordance with the TTU-HIV project led by Prof. Behrens in Hannover.

2. TopHIVpast cohort:

HIV infected patients that were identified in the acute phase (Fiebig I – V) in the past years will be enrolled in the cohort. Recruitment will be performed at the HIV outpatient department of the Infectious Diseases Unit, LMU, Munich, the Schwabinger Krankenhaus and at collaborating private practices (e.g. Dr. Jäger). As a control group, we will also include patients who did not start ART in the acute phase of infection. Data collection will be started.

3. TopHIVfuture cohort:

Again recruitment will be performed at the HIV outpatient department of the Infectious Diseases Unit, LMU, Munich and at collaborating private practices (e.g. Dr. Jäger). Included will be men and women who present with Fiebig stages I - V and it will be monitored if they start ART or not. It is planned to specifically target patients with known dates of primary HIV infection (defined by original western blots). Clinical data and biomaterial collection will be done in close collaboration with Prof. Behrens, Hannover and according to a jointly developed protocol.

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

The goal of this pilot grant is to initiate the cohorts required for a national multi-center primary HIV infection cohort. We will establish the requirements with regard to ethical approval, collaboration with external Munich sites (e.g. private practices) and patient recruitment. Importantly, this project is planned to turn into one part of the multi-center cohort.

1. Ethical approval:

Study protocol, patient consent form and IRB application will be prepared in accordance with the TTU-HIV project led by Prof. Behrens in Hannover.

2. TopHIVpast cohort:

HIV infected patients that were identified in the acute phase (Fiebig I – V) in the past years will be enrolled in the cohort. Recruitment will be performed at the HIV outpatient department of the Infectious Diseases Unit, LMU, Munich, the Schwabinger Krankenhaus and at collaborating private practices (e.g. Dr. Jäger). As a control group, we will also include patients who did not start ART in the acute phase of infection. Data collection will be started.

3. TopHIVfuture cohort:

Again recruitment will be performed at the HIV outpatient department of the Infectious Diseases Unit, LMU, Munich and at collaborating private practices (e.g. Dr. Jäger). Included will be men and women who present with Fiebig stages I - V and it will be monitored if they start ART or not. It is planned to specifically target patients with known dates of primary HIV infection (defined by original western blots). Clinical data and biomaterial collection will be done in close collaboration with Prof. Behrens, Hannover and according to a jointly developed protocol.

Chapter 2: Detailed description

a) Use of funding (for the project) and a detailed description of the achieved results compared to the original aims of the project description. Please also address the individual milestones and deliverables (as listed in chapter 4 of this report). Please note: All your information has to refer to the entire project duration.

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

Main project: Initiation of TopHIV cohort:

1.) Deliverable 1: The study protocoll was designed in close collaboration with Prof. Dr. Georg Behrens and his group at the MHH and has then been communicated by us to the lab personel in Munich. There are 4 private practices (MVZ am Stachus, Prinzmed, Praxis am Isartor, ZIMI) involved in this study in Munich. Our site is the coordinator of the Munich site. We have communicated the study protocoll to the other sites in Munich and have held meetings to make sure everybody is informed about all necessary actions. So this deliverable is completed.

2.) Deliverable 2: The patient information was designed mainly by PD Dr. Janne Vehreschild of the University Hospital in Cologne and was then submitted to the IRB committee of the University Hospital in Munich and a positive decision was reached. Therefore patients can be actively recruited and also this deliverable is completed.

3.) Milestone 1: Start of patient recruitment: It was planned to enroll the first patient by October 2015. Due to the delay of the start of the multicenter study in all centers, we enrolled our first patient on Feb. 8th 2016. This milestone was slightly delayed.

4.) Milestone 2: Evaluation of MDSC: It was planned to start the assessment of MDSC in study patients in October 2015. Due to the delay of the start of the multicenter study in all centers, we assessed the first MDSC on Feb. 8th 2016. Also this milestone was slightly delayed.

Due to the delay of the start of enrollment into the TopHIV cohort, resourses were also used to work on other projects that were preparatory work for the TopHIV cohort and other projects funded by the DZIF. Among them were:

1.) Assessment of kinetics of human MDSC after blood draw.

Background: Human myeloid-derived suppressor cells (MDSC) have been described as a group of immature myeloid cells which exert immunosuppressive action by inhibiting function of T lymphocytes. While there is a huge scientific interest to study these cells in multiple human diseases, the methodological approach varies substantially between published studies. This is problematic as human MDSC seem to be a sensible cell type concerning not only cryopreservation but also time

point after blood draw. To date data on delayed blood processing influencing cell numbers and phenotype is missing. We therefore evaluated the kinetics of granulocytic MDSC (gMDSC) and monocytic MDSC (mMDSC) frequencies after blood draw in order to determine the best time point for analysis of this recently defined cell type.

Methods: In this study, we isolated peripheral blood mononuclear cells (PBMC) of patients with HIV infection or solid tumors directly after blood draw. We then analyzed the frequencies of gMDSC and mMDSC 2, 4 and 6 hours after blood draw and after an overnight rest by FACS analysis using the standard phenotypic markers. In addition, part of the cells was frozen directly after PBMC preparation and was measured after thawing.

Results: gMDSC levels showed no significant difference using fresh PBMC over time with a limitation for the overnight sample. However they were massively diminished after freezing ($p=0.0001$ for all subjects). In contrast, frequencies of fresh mMDSC varied over time with no difference between time point 2h and 4h but a significantly reduction after 6h and overnight rest ($p=0.0005$ and $p=0.005$ respectively). Freezing of PBMC decreased the yield of mMDSC reaching statistical significance ($p=0.04$). For both MDSC subgroups, FACS analysis became more difficult over time due to less sharp divisions between populations.

Conclusions: According to our data human MDSC need to be studied on fresh PBMC. gMDSC can be studied with delay, mMDSC however should be studied no later than 4h after blood draw. These results are crucial as an increasing number of clinical trials aim at analyzing MDSC nowadays and the logistics of blood processing implies delayed sample processing in some cases.

This study was published by the end of 2015 (see attached file: 504 UK LMU_Kapitel3a_Datei1_Publikation_Grützner). The results are extremely important for the conduction of MDSC studies in the TopHIV cohort because we know now that MDSC can only be studied in fresh PBMC!

2.) Collection and processing of blood samples as well as analysis of inhibitory immunological mechanisms in the NewEra cohort - another project funded by the DZIF

We collected and processed blood samples of almost all NewEra patients in the southern part of Germany. The PBMC were partly frozen for other collaborating labs in Germany (e.g. Julian Schulze zur Wiesch in Hamburg; Marcus Altfeld in Hamburg). Partly, the samples were used to study inhibitory immunological mechanisms in this very special patient cohort. In detail we studied the frequencies of gMDSC, mMDSC, regulatory B cells and regulatory T cells as well as the CD8 T cell responses towards the HIV proteins Gag and Nef. The work is on-going but we have submitted abstracts about the preliminary results for the KIT 2016.

This work is important as it shows the immunologcal situation of HIV infected patients treated extremely early in the disease course. It is also crucial in view of the TopHIV cohort as we also want to study these parameters in the TopHIV cohort and therefore needed to establish all methods

b) Necessity and adequacy of the work done

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

As stated above the milestones 1 and 2 could only be reached with slight delay. This was due to a delayed start of the whole study in Germany.

As the patient enrollment was delayed, Mrs. Stirner had time to work on other - however TopHIV cohort related - projects as described in detail above.

c) Prospective benefit, in particular the usability of the results according to the exploitation plan

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

As the patient enrollment started in Feb. 2016, there are not enough results from the TopHIV cohort yet to assess its prospective benefit.

As for the other projects:

1.) Kinetics of human MDSC after blood draw: We know that MDSC can only be studied from fresh cells in order to reflect the actual situation in vivo. This is extremely important for the planning of the sample processing and assessment in the big multicenter cohort of TopHIV.

2.) Assessment of the NewEra patients: The results will give a valuable control group for the TopHIV patients and their results.

d) Results of third parties

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

The study protocoll was mainly designed by Prof. Dr. Georg Behrens and his group at the Medizinische Hochschule Hannover.

The patient information was designed by PD Dr. Janne Vehreschild and his group at the University Hospital in Cologne.

Chapter 3: Success control report

Chapter 3.1: Detailed presentation of the success / exploitation prospects

a) Technology transfer office

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☒ No information possible

Name	Contact person	Comment

b) Inventions / patent applications

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☒ No information possible

Title	Inventor	Comment, invention notification exists [yes/no]

c) Intellectual property rights granted

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☒ No information possible

Title	Inventor	Comment

d) Licences

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☒ No information possible

Title	Licensee	Comment

e) Cooperation agreements (incl. letter of intent)

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☐ No information possible

Theme	Partner	Comment
Enrollment of patients in the TopHIV cohort	Prof. Dr. Georg Behrens, MHH Hannover	

f) Contracts with industry

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☒ No information possible

Theme	Partner	Comment

g) Patents

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☒ No information possible

Patent holder	Patent number	Comment

h) Clinical trials

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☒ No information possible

DZIF Principle investigator	Title	Hypothesis to be tested	Mono/multicenter	Phase [I - IV]	Partner sites involved	Design [e.g. double blind]	Planned recruiting	Achieved recruiting	Registration No.	Original data accessible [yes/no]

i) Confirmatory preclinical trials

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☐ No information possible

DZIF Principle investigator	Title	Hypothesis to be tested	Cell culture or animal models used, type	Partner sites involved	Type [e.g. ADME tox, etc.]	Original data accessible [yes/no]
Prof. Dr. Rika Draenert	Kinetices of human MDSC after blood draw	Can MDSC measured after delay or after freezing?	Human PBMC	LMU Munich		yes

j) Cohorts

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☐ No information possible

Title	Mono/multicenter	Partner sites involved	Planned recruiting	Achieved recruiting
NewEra study patients	multicenter	LMU Munich; MVZ	all NewEra patients	95%

		Stachus; Praxis am Isartor; private practice in Stuttgart, private practice in Mannheim		
TopHIV patients	multicenter	all DZIF HIV sites;	30 patients per year	3 this year

k) Data and biomaterial banks

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☐ No information possible

Title	**Amount/number of data, (bio)material**	**Comment on the development of materials and data over time**	**Usage**			
			Number of accesses/entities	**Number of users**	**Title of involved DZIF projects**	**Involved external projects**
NewEra study	PBMC; plasma	stored at our site so far;		So far: 1	NewEra Amendment 1.0	
TopHIV cohort	PBMC; plasma	stored at our stie so far;		So far: 1	Treatment strategies in primary HIV-1 infection to cure HIV - TopHIV	

l) Publications

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)
DZIF author at the site: Draenert R

☐ No information possible

Authors	Title	Journal	Vol, issue; pages	Year	doi	Impact factor
Grützner E, Stirner R, Arenz L, ... Draenert R	Kinetics of human myeloid-derived suppressor cells after blood draw	Journal of Translational Medicine	Vol. 14; pages 2ff	2016	DOI 10.1186/s12967-015-0755-y	3.93

Chapter 3.2: Collaboration with other partners

a) Cooperations within the DZIF

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☐ No information possible

Who	Where	Comment/scope
Prof. Dr. Georg Behrens	MHH Hannover	Principle Investigator of TopHIV study
PD Dr. Janne Vehreschild	University Hospital Cologne	IRB and study coordinator
PD Dr. Christof Geldmacher	LMU Munich	Assessment of immunological mechanisms and viral reservoir in TopHIV patients
Prof. Dr. Florian Klein	University Hospital Cologne	Plasma sample collection for assessment of broadly neutralizing antibodies

b) External German partners

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☐ No information possible

Who	Where	Comment/scope
Dr. Hans Jäger	MVZ Stachus Munich	Patient recruitment
Dr. Ramona Pauli, Dr. Werner Becker	Praxis am Isartor Munich	Patient recruitment
Dr. Nils Postel	Prinzmed Munich	Patient recruitment
Dr. Anja Meurer, Dr. Ulrich Kastenbauer	ZIMI Munich	Patient recruitment

c) German industrial partners

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☒ No information possible

Who	Where	Comment/scope

d) International academic partners

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☒ No information possible

Who	Where	Comment/scope

e) International industrial partners

Project: TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)

☒ No information possible

Who	Where	Comment/scope

Chapter 4: Comparison: Current status of the project with original information

a) Milestones

No.	Title	Work package	Institution	Date as per application	Corrected date	Status	Comment
1	Start of recruitment	First patient in the study	Klinikum der Universität München	31.10.2015	08.02.2016	delayed	Start of multicenter study delayed.
2	Evaluation of MDSC	Assessment of frequency of MDSC in all patients	Klinikum der Universität München	31.10.2015	08.02.2016	delayed	Start of multicenter study delayed.

b) Deliverables

No.	Title	Work package	Institution	Date as per application	Corrected date	Status	Comment
1	Study protocoll	Writing of study protocoll	Klinikum der Universität München	31.10.2015	15.10.2015	completed	
2	IRB application	Submission of IRB application and dicision by IRB committee	Klinikum der Universität München	31.12.2015	27.10.2015	completed	

Chapter 5: Most important items of the financial report

a) Funding for staff

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)
Use: We only had funds from April 2015 till December 2015.Mrs Renate Stirner was employed as MTLA (E9, 78% = 30 hours/week) in April 2015.Mrs. Renate Stirner was employed as MTLA (E9, 42% = 16 hours/week) from May 2015 till December 2015.
Circumstances: Funds were not completely used because unfortunately the deadline for extension of the funding period was not communicated to me.

b) Consumables

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)
Use: None.
Circumstances:

c) Investment funds

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)
Use: None.
Circumstances:

d) Travel expenses

TTU 04.809 - The Munich Early HIV infection cohort pilot study (MEICP study) (Klinikum der Universität München)
Use: None.
Circumstances:

Berichtsblatt

1. ISBN oder ISSN Geplant (teilweise: ISSN 1479-5876)	2. Berichtsart (Schlussbericht oder Veröffentlichung) Schlussbericht

3. Titel
Pilotstudie der pimären HIV-Infektions-Kohorte in München (MEICP)

4. Autor(en) [Name(n), Vorname(n)] Prof. Dr. med. Rika Draenert	5. Abschlussdatum des Vorhabens 31.12.2015
	6. Veröffentlichungsdatum 29.06.2016
	7. Form der Publikation
8. Durchführende Institution(en) (Name, Adresse) Klinikum der Universität München Medizinische Klinik und Poliklilnik IV Sektion Klinische Infektiologie Pettenkoferstr. 8a 80336 München	9. Ber. Nr. Durchführende Institution TTU 04.809
	10. Förderkennzeichen 8026804811
	11. Seitenzahl 21
12. Fördernde Institution (Name, Adresse) Bundesministerium für Bildung und Forschung (BMBF) 53170 Bonn	13. Literaturangaben 1
	14. Tabellen 7 (mit Information)
	15. Abbildungen 0

16. Zusätzliche Angaben

17. Vorgelegt bei (Titel, Ort, Datum)

18. Kurzfassung

Ein großes Ziel in der HIV-Forschung ist die funktionelle Heilung, d.h. dass HIV-Infizierte selbst, auch ohne antiretrovirale Therapie, die Infektion kontrollieren können. Für dieses Ziel sind Patienten, die in der primären HIV-Infektion mit einer antiretroviralen Therapie behandelt werden, sehr interessant. Die DZIF TTU HIV ist dabei, eine deutschland-weite Kohorte an Patienten aufzubauen, die sich in der akuten HIV-Infektion vorstellen. Im berichteten Projekt soll hierfür eine Pilotstudie durchgeführt werden. Alle Voraussetzungen für die Patientenrekrutierung wurden geschaffen, insbesondere Ethikvotum eingeholt, Kollaborationen in München mit niedergelassenen Ärzten aufgebaut und labortechnische Voraussetzungen geklärt. Am Ende der Förderperiode wurden die ersten Patienten eingeschlossen. Das Blut wurde verarbeitet und erste Messungen zu inhibitorischen immunologischen Mechanismen durchgeführt. Die Patienten werden gesammelt, um zunächst Korrelate der Immunantwort in der akuten HIV-Infektion zu bestimmen. Später soll die Kohorte jedoch auch für Interventionsstudien Verwendung finden. Aufgebaut wird die Kohorte in enger Kollaboration mit Prof. Dr. G. Behrens und seiner Arbeitsgruppe.

19. Schlagwörter
Primäre HIV-Infektion – funktionelle Heilung – nationale Kohortenstudie – Korrelate der Immunkontrolle

20. Verlag	21. Preis

Document Control Sheet

1. ISBN or ISSN Planned (partly: ISSN 1479-5876)	2. type of document (e.g. report, publication) Report
3. title The Munich Early HIV infection cohort pilot study (MEICP study)	
4. author(s) (family name, first name(s)) Prof. Dr. med. Rika Draenert	5. end of project Dec. 31st 2015
	6. publication date June, 29th 2016
	7. form of publication
8. performing organization(s) (name, address) Klinikum der Universität München Medizinische Klinik und Poliklinik IV Sektion Klinische Infektiologie Pettenkoferstr. 8a 80336 München	9. originator's report no. TTU 04.809
	10. reference no. 8026804811
	11. no. of pages 21
12. sponsoring agency (name, address) Bundesministerium für Bildung und Forschung (BMBF) 53170 Bonn	13. no. of references 1
	14. no. of tables 7 (with information)
	15. no. of figures 0
16. supplementary notes	
17. presented at (title, place, date)	
18. abstract One of the goals in HIV research is the achievement of a functional cure, i.e. that HIV infected subjects can control their infection without antiretroviral treatment. For this purpose, patients with primary HIV infection which are treated directly with antiretroviral treatment are especially interesting. At the moment, the DZIF TTU HIV builds a nation-wide cohort of such patients. In this project, we conducted a pilot study for this. All prerequisites are in place, in particular the approval of the ethical committee was obtained, collaborations with private practices in Munich established and technical necessities settled. At the end of the funding period, the first patients were included in the study. The blood was processed and the first assays for the assessment of inhibitory immunological mechanisms were conducted. These patients are collected in order to assess correlates of immune control first. In the next step, they will be needed to test new therapeutic approaches for a cure strategy in clinical trials. This work is done in close collaboration with Prof. Dr. G. Behrens.	
19. keywords Primary HIV infection – functional cure – national cohort study – correlates of immune control	
20. publisher	21. price