ISRCTN63722214 https://doi.org/10.1186/ISRCTN63722214

Worms and human immunodeficiency virus (HIV) Interaction Study - Epidemiology component

Submission date	Recruitment status	[_] Prospectively registered
03/07/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/08/2009	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Elmar Saathoff

Contact details
Leopoldstr. 5
Munich
Germany
80802
+49 (0)89 2180 3830
elmarsaathoff@web.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DFG protocol No.: SA 1878/1-1

Study information

Scientific Title
Intestinal helminth infections and schistosomiasis and their relation to human immunodeficiency virus-1 (HIV-1) incidence, disease progression and immunology in Mbeya Region, Tanzania - epidemiology component

Acronym
WHIS_Epi

Study objectives
1. The incidence of human immunodeficiency virus-1 (HIV-1) infection in initially HIV negative participants is reduced after targeted treatment of helminth infections (after diagnosis) when compared to initially HIV negative participants who have neither been examined nor treated for helminth infections
2. HIV disease progression and the onset of acquired immune deficiency syndrome (AIDS) in HIV-1 positive participants is delayed after targeted treatment of helminth infections (after diagnosis) when compared to HIV positive participants who have neither been examined nor treated for helminth infections

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Institutional Review Board (IRB) in Munich (Ethikkommission der Medizinischen Fakultät der LMU Muenchen) approved on the 3rd April 2009.

Approval for collection of required data and to treat helminth infections:
1. National Institute of Medical Research (NIMR) Institutional Review Board (IRB), gained in 2005
2. Mbeya Medical Research and Ethics Committee, gained in 2006

Approval to use the obtained data for this study has been applied for with the two above local IRBs but is still pending.

Study design
Observational longitudinal study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Human immunodeficiency virus-1 (HIV-1) infection/helminth infections

Interventions
This is an observational longitudinal study, implemented within the framework of a large, household based single-centre population-based cohort study (EMINI), which is conducted by the Mbeya Medical Research Programme in cooperation with Munich University.

EMINI cohort activities started in 2006 involving ~18500 participants of all ages and both sexes from 4283 households. Thus most potential WHIS_Epi participants have already been followed up since then (exception: new household members). Since the start of EMINI, participating households have been visited annually, in order to collect lab samples and interview data regarding HIV, malaria, tuberculosis (Tb) and other infectious diseases from all consenting household members.

In August 2008, examination for intestinal nematode infection and schistosomiasis (using Kato-Katz faecal thick smears and urine filtration) and standard helminth treatment was introduced in parts of the EMINI population. In accordance with national Tanzanian (TZ) guidelines treatment is 400 mg albendazole for participants older than 3 years and 200 mg albendazole for participants younger than 3 years from households where intestinal nematode infections were found, and 40 mg praziquantel per kg for individual treatment of diagnosed schistosomiasis infection. Due to logistic and financial constraints we were initially only able to offer these services to only half of the participating households.

However, during the next round of follow-up starting 1st August 2009, all study participants will receive diagnosis for helminth infection and treatment if needed. The WHIS-Epi study will link data of previous helminth infection and respective treatment with data on HIV incidence and disease progression in both parts of the EMINI cohort.

Joint/scientific contact details:
Dr Leonard Maboko
Managing Director of MMRP
Mbeya Medical Research Programme
Mbeya
Tanzania

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Hypothesis 1: Seroconversion to HIV since last study visit; applied tests:
1.1. Initial HIV screening with SD Bioline HIV1/2
1.2. Positive results retested with Enzygnost HIV1/2 Plus
1.3. Discordant results confirmed by Western Blot
2. Hypothesis 2:

2.1. Change in Karnofsky score
2.2. HIV staging
2.3. Presence/absence of opportunistic infections (all determined by medical examination)
2.4. Changes in viral load

Assessed one and two years after deworming.

Secondary outcome measures
1. Prevalence of intestinal nematode infections and schistosomiasis in the study population, measured before worm treatment
2. Effect of albendazole and praziquantel treatment on helminth infection, measured one and two years after deworming
3. Helminth reinfection after deworming, measured one and two years after deworming

Intestinal nematode and S. mansoni infection for all above outcomes will be diagnosed by Kato-Katz microscopy, S. haematobium infection by urine filtration and microscopy.

Overall study start date
01/08/2009

Completion date
31/07/2011

Eligibility

Key inclusion criteria
Participation in the EMINI cohort study. Participants of all age groups and both sexes will be included.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
18500

Key exclusion criteria
The study will only include consenting members of households who participate in the EMINI study, no other exclusion criteria apply.

Date of first enrolment
01/08/2009

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
Germany

Tanzania

Study participating centre
Leopoldstr. 5
Munich
Germany
80802

Sponsor information

Organisation
Department for Infection and Tropical medicine (Abteilung fuer Infektions- und Tropenmedizin) (Germany)

Sponsor details
Abteilung fuer Infektions- und Tropenmedizin
Ludwig-Maximilans-University (LMU) Munich University Hospital
Leopoldstr. 5
Munich
Germany
80802
+49 (0)89 2180 3830
tropinst@lrz.uni-muenchen.de

Sponsor type
Hospital/treatment centre

Website
http://www.tropinst.med.uni-muenchen.de

ROR
https://ror.org/05591te55

Funder(s)

Funder type
Research council

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) (ref: SA 1878/1-1)

Funder Name
European Commission (Belgium) - DGVIII AIDCO (donor of EMINI) (ref: SANTE/2006/129-931)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration