Research towards presence of Antibodies against European Bat Lyssavirus (EBLV) after immunization with Rabipur®

Published: 16-07-2012
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Primary objective:A. Development of human monoclonal antibody or combination thereof for the treatment of Rabiës and Rabiës-like viruses that might provide an affordable and accessible alternative to current polyclonal preparations. Particular...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON37212

Source
ToetsingOnline

Brief title
AER-2012

Condition

- Viral infectious disorders

Synonym
rabies

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Crucell Holland BV

Intervention

Keyword: Antibodies, European Bat Lysa Virus, Immunisation, Rabipur

Outcome measures

Primary outcome

The primary goal is to obtain PBMC*s of Rabipur® vaccinated individuals.

Secondary outcome

demonstrate antibodies that are able to bind other lyssavirus genotypes, in

particular EBLV.

Study description

Background summary

: There is a need for a better and more efficient treatment of Rabiës infections, in particular the treatment of the newly emerging Rabiës related viruses like European Bat Lyssavirus (EBLV). The aim of this study is to identify human antibodies that can be used for the post-exposure prophylaxis (PEP) treatment against Rabiës and Rabiës related diseases.
For that reason, human B-cells of donors that were recently vaccinated with the commercially available Rabiës vaccine Rabipur® are needed. The genetic material coding for immunoglobulins will be isolated from these B-cells and subsequently used in phage display technology to select antibodies directed against Rabiës and Rabiës related viruses, in particular against EBLV. These monoclonal antibodies will be tested for clinical development

Study objective

Primary objective:
A. Development of human monoclonal antibody or combination thereof for the treatment of Rabiës and Rabiës-like viruses that might provide an affordable and accessible alternative to current polyclonal preparations. Particular attention is given to the treatment of Rabiës-related European bat lyssavirus variants that are endemic within different bat populations in Europe.

Secondary objectives:
B. Development of a human monoclonal antibody or combination with broad neutralizing action against Rabiës like viruses, which can be used as an

alternative for the current RIG therapy that is less expensive, more efficient and safer.
C. This study might provide information if vaccinated individuals that were prophylactic vaccinated with Rabipur® generate antibodies that are able to bind other lyssavirus genotypes, in particular EBLV.

Study design

Single centre clinical trial.
Healthy individuals will be vaccinated with approved drug; Rabipur®. One week after primary and secondary vaccination heparin blood will be drawn. Blood will be used to isolate PBMC*s.
No critical parameters are set on this study

Study burden and risks

Expected risk: Not significant, since it concerns an approved vaccine.
Administration of Rabipur® will be according to package insert
Discomfort: discomfort associated with blood sampling, i.e twice 50 ml.
Benefits: Prophylactic vaccination against Rabiës

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age between 18 and 65 year
Healthy

Exclusion criteria

A know or suspected allergy towards one of the components of the vaccine, i.e. chicken protein, polygeline, neomycin, chlorotetracyclin and amfotericine B.
History of serious allergic reactions
Use of medication to suppress immune response
A chronic disease that affects the immune system, systemic diseases such as SLE, ANCA associated vasculitis
Pregnancy or actual child wish (upon inquiry at the time of screening)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-03-2013
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Rabipur

Ethics review

Approved WMO Date:	16-07-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	29-10-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-002096-34-NL
CCMO	NL40653.058.12