A Phase I, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and T-cell tolerizing effect of DC-TAB in healthy volunteers, after single and multiple dosing

Published: 12-11-2009
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To evaluate the safety and tolerability of DC-TAB following a single dose and following repeated dosing in healthy volunteers. To assess the pharmacokinetics of DC-TAB following a single dose and following repeated dosing in healthy volunteers. To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system infections and inflammations
Study type	Interventional

Summary

ID

NL-OMON34913

Source
ToetsingOnline

Brief title
A phase I trial with DC-TAB

Condition

- Central nervous system infections and inflammations

Synonym
Multiple sclerosis, nervous system disease

Research involving

Human

Sponsors and support

Primary sponsor: Delta Crystallon BV
Source(s) of monetary or material Support: Delta Crystallon BV

Intervention

Keyword: DC-TAB, Multiple sclerosis, Phase I trial

Outcome measures

Primary outcome

To evaluate the safety and tolerability of DC-TAB following a single dose and

following repeated dosing in healthy volunteers.

Secondary outcome

To assess the pharmacokinetics of DC-TAB following a single dose and following

repeated dosing in healthy volunteers.

To evaluate the T-cell tolerizing effect of DC-TAB in healthy volunteers. To

evaluate levels of DC-TAB specific and -neutralizing antibodies.

Study description

Background summary

DC-TAB is recombinant protein resembling a substance which normally exists in the human body: the alpha B-crystalline (cryab). This substance protects normal cells in the nervous system. In humans, a natural response is present against cryab. This response is to powerful in patients with MS and causes inflammations of the nervous system and causes the symptoms of MS. By treating subjects with DC-TAB, the immune system will tolerate this substance (cryab) and will possibly reduce the inflammations causing MS and the symptoms of MS may diminish or stabilize.

Study objective

To evaluate the safety and tolerability of DC-TAB following a single dose and following repeated dosing in healthy volunteers. To assess the pharmacokinetics of DC-TAB following a single dose and following repeated dosing in healthy volunteers. To evaluate the T-cell tolerizing effect of DC-TAB in healthy volunteers. To evaluate levels of DC-TAB specific and -neutralizing antibodies.

Study design

A double-blind and randomized, study.

Intervention

The study consists of 2 parts. In Part 1, all subjects will receive a single dose of study medication on day 1; in Part 2, different subjects will receive medication once daily during 3 consecutive days.
In Part 1, four groups of subjects (n=10) will be studied in a dose-escalation design. Each group of subjects will be randomized to receive either DC-TAB (n=8) or placebo (n=2) once.
In Part 2, three groups of subjects (n=12) will be studied in a dose-escalation design. Each group of subjects will be randomized to receive either DC-TAB (n=9) or placebo (n=3) once daily on 3 consecutive days.

Study burden and risks

The risks associated with this investigation are linked together with the possible side effects of the dosing via a bolus injection and the investigational product (e.g. allergic reaction). The burden on the volunteer consists of a confinement during recording periods, venapunctures and the introduction of the cannulas. All volunteers are closely monitored and supervised by experienced doctors and study staff for possible side effects and adverse reactions.

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

• you have given your written consent to take part in this study;
• you are between 18 and 55 years of age (inclusive);
• you are in good physical and mental health;
• your body weight must be appropriate in relation to your height;
•The use of suitable anti conception in the 3 months before start of the study and you will remain using this until 3 months after the study and/or you can not invoke an pregnancy (males) or you can not get pregnant (females)
• no abnormalities are diagnosed during the screening.

Exclusion criteria

•If you are pregnant, planning to get pregnant or breastfeeding;
•If you have relatives (1st degree) who have MS;
•If you smoke 5 or more cigarettes per day or are not able to stop smoking during the admission period;
•If you have abused drug (past and present) and or alcohol
•The use of prescribed medication in the 14 days before start of the study, except for hormone based anticonceptionals, standard vitamines and paracetamol;
•If you recieved a vaccination within the 4 weeks before the start of the study;
•you have taken part in another clinical drug study during the last 3 months prior to the study;
• you have donated blood in the three months before admission;
•you have donated plasma in the 7 days before admission;
•if you have recieved bloodproducts in the 6 month before start of start of the study;

• you are Hepatitis B, C or HIV positive;
If no immune response can be achieved by DC-TAB in your blood;
•you are not suitable to participate in this study according to the investigator.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-12-2009
Enrollment:	76
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	DC-TAB

Ethics review

Approved WMO

Date:	12-11-2009
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	19-11-2009
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-11-2009
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-11-2009
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-03-2010
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-03-2010
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-07-2010
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-07-2010
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2009-016817-68-NL
CCMO	NL30321.040.09