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Ethical protocol for blood sampling from healthy adult volunteers for research on the immune answer towards biotherapeutic drugs in development

Submission date
01/06/2015

Recruitment status
No longer recruiting

Registration date
01/07/2015

Overall study status
Completed

Last Edited
18/11/2021

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nanobodies® are a recently discovered class of proteins, which show great therapeutic and diagnostic potential in diseases such as cancer. They have many advantages over classical biotherapeutics (engineered biological products), but since Nanobodies originate from camelid animals (e.g. camels and alpacas) there is a risk of unwanted side effects, particularly immune system responses, when used in humans. These responses may drastically limit how effective the therapy is, and in certain cases can even be very harmful for the patient. The aim of this study is to investigate the cause of unwanted immune system reactions to Nanobodies. Specifically, this study will examine the non-human (camelid) aspects of the Nanobodies protein, production side-products and formulation to analyse the main steps responsible for inducing an immune response in humans. This will be done by taking blood samples from healthy volunteers, which will then be analysed in the laboratory to isolate specific, highly sensitive cells that are known to be critical in initiating an immune system response.

Who can participate?
Healthy adults aged 18-65.

What does the study involve?
All participants are asked to give a blood sample.

What are the possible benefits and risks of participating?
The results of this study will be used to generate safer and more efficient Nanobodies, resulting in healthier patients and reduced health costs.

Where is the study run from?
1. Free University of Brussels (Vrije Universiteit Brussel) (Belgium)
2. University Hospital Brussels (Universitair Ziekenhuis Brussel) (Belgium)

When is the study starting and how long is it expected to run for?
July 2015 to June 2018

Who is funding the study?
Free University of Brussels (Vrije Universiteit Brussel) (Belgium)

Who is the main contact?
Dr C Ackaert

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Ethical protocol for blood sampling from healthy adult volunteers for research on risk mitigation of immunogenicity of Nanobodies®

Study objectives
Rationale of the study: to determine immunogenic regions in the sequence of Nanobodies to be able to change these regions to generate more safe and less immunogenic Nanobodies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University Hospital Brussels (UZ Brussel), Belgium - submission planned for 05/06/2015.

Study design
Single-centre trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Blood sampling from healthy, adult volunteers for isolation of peripheral blood mononuclear cells (PBMCs) for in vitro analysis of the human immune response towards Nanobodies.

Interventions
Blood sampling (up to 450 ml). Nothing is administered.

Intervention Type
Procedure/Surgery

Primary outcome measure
T cell proliferation and differentiation in vitro as surrogate marker for the in vivo development of anti-drug antibody formation, measured 1-2 weeks after blood sampling.

Secondary outcome measures
Immunogenic regions of the Nanobodies are identified and mutated, and the resulting new Nanobodies are tested once again for immunogenicity. Measurements are carried out 2.5 years after blood sampling.

Overall study start date
01/07/2015

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Good general health
2. Aged 18-65

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Pregnant (in case of doubt, a test will be taken) or envisages a pregnancy in the near future
2. History of significant inconvenience with blood sampling
3. High risk for HIV, HBV or HCV
4. Has received blood or blood products in the last 6 months
5. Has received any therapeutic treatment that influences the immune system
6. Presence of acute or chronic infection or disease
7. Currently taking drugs, except for contraceptives
8. Associated with the current study

Date of first enrolment
01/07/2015

Date of final enrolment
01/06/2018

Locations

Countries of recruitment
Belgium

Study participating centre
Free University of Brussels (Vrije Universiteit Brussel)
Boulevard de la Plaine 2

Elsene
Belgium
1050

Study participating centre
University Hospital Brussels (Universitair Ziekenhuis Brussel)
Avenue du Laerbeek 101
Jette
Belgium
1090

Sponsor information

Organisation
Vrije Universiteit Brussel

Sponsor details
Pleinlaan 2
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Sponsor type
University/education

ROR
https://ror.org/006e5kg04

Funder(s)

Funder type
University/education

Funder Name
Free University of Brussels (Vrije Universiteit Brussel)

Results and Publications

Publication and dissemination plan

Publication 1: Response of dendritic cells to Nanobodies: planned beginning 2016
Publication 2: Response of T cells to Nanobodies: planned end 2016
Publication 3: Optimised sequence of Nanobodies with reduced immunogenicity: planned half 2018

Intention to publish date
01/01/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/03/2021	18/11/2021	Yes	No