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LEISH1: A study to assess the safety and immunogenicity of a new Leishmania vaccine candidate ChAd63-KH

Submission date
03/05/2013

Recruitment status
No longer recruiting

Registration date
03/05/2013

Overall study status
Completed

Last Edited
01/03/2019

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Leishmaniasis is a parasitic disease that is spread from an infected animal or person to another by bites from a sand fly. It mostly affects the worlds poorest people in India, Bangladesh, Nepal, the Sudan and Brazil. About 70,000 people, mostly children and young adults, die of Leishmaniasis each year, and hundreds of thousands develop skin ulcers that cause unsightly or disfiguring scars. In its most severe form Leishmaniasis affects internal organs such as the liver and spleen and it is this form that is usually fatal if not treated. Although drugs for the treatment of Leishmania are available they are extremely costly and resistance to these drugs is beginning to develop. There is also no effective preventative vaccine currently available. However, the vaccine in this study is not designed to prevent people from getting Leishmaniasis but to lower the levels of parasite within the body to enable other treatments to work more effectively. This is known as a therapeutic vaccine. This is a first in human study which aims to assess the safety of this new vaccine in healthy people, and to look at how well the immune system responds to this vaccine by testing blood in the laboratory.

Who can participate?
Healthy adults aged between 18 and 50

What does the study involve?
There are two doses of the vaccine used in this study - a low dose and a higher dose. This is to compare the difference in side effects and responses to the vaccine depending on how much of the vaccine is given.

What are the possible benefits and risks of participating?
As this is a study involving healthy volunteers they will not gain any direct medical benefit from participating in this study. Participants may experience side effects from the vaccine in this study, similar to the side effects that occur after immunisations. This could include fevers, chills, general muscle aches (like flu), feeling unusually tired, headache, nausea, or discomfort, redness or swelling at the injection site (upper arm). Because this vaccine has not been used before in humans, not much is known about the side effects. This means that the side effects listed above

could be worse than expected and there may be other unknown side effects. It is possible if the vaccine is given to a pregnant woman it will harm the unborn child. This is why we need women to use an effective form of contraception and to have pregnancy tests before the immunisation. Any woman who finds that she has become pregnant while taking part in the study should immediately tell her study doctor. Blood sampling can sometimes cause bruising and soreness of the arms or very rarely a blockage of the vein or a small nerve injury which can cause numbness and pain. Normally these problems resolve with time. Some people may faint while blood is being taken. Rarely some people experience a reaction to receiving a vaccine which can be serious. If this occurs it is likely to happen shortly after receiving the vaccine. For safety participants are required to stay in the clinic for 2 hours after the vaccination and there will be a doctor and a nurse present with them during this time.

Where is the study run from?
York Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2013 to March 2014

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Ms Carol Taylor
carol.taylor@york.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Ms Carol Taylor

Contact details
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Additional identifiers

EudraCT/CTIS number
2012-005596-14

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14052

Study information

Scientific Title
A phase I study to assess the safety and immunogenicity of a new Leishmania vaccine candidate ChAd63-KH

Study objectives
The aim of this study is to assess the safety of a new vaccine in healthy people, and to look at how well the immune system responds to it.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - York Research Ethics Committee, 08/03/2013, ref: 13/NE/0071

Study design
Non-randomised interventional trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Topic: Infection; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

Interventions
The first five volunteers will receive 1x10(10) vp the subsequent fifteen volunteers will receive 7.5x10(10) vp. Doses will be administered at a single time point to healthy volunteers.

Vaccination, a single intramuscular dose of ChAd63-KH 7.5x1010 vp

Follow Up Length: 3 months

Intervention Type

Biological/Vaccine

Phase
Phase I

Drug/device/biological/vaccine name(s)
ChAd63-KH

Primary outcome measure
Safety and reactogenicity, actively and passively collected data on adverse events

Secondary outcome measures
Immunogenicity: markers of humoral and cell-mediated immunity

Overall study start date
16/04/2013

Completion date
31/03/2014

Eligibility

Key inclusion criteria
1. Male and female aged 18 to 50 years on the day of screening
2. Available for the duration of the study
3. Willing and able to give written informed consent
4. In good health as determined by medical history, physical examination, results of screening tests and the clinical judgment of a medically qualified Clinical Investigator
5. Judged, in the opinion of a medically qualified Clinical Investigator, to be able and likely to comply with all study requirements as set out in the protocol
6. Willing to undergo screening for HIV, Hepatitis B and Hepatitis C
7. Agree to refrain from blood donation for the duration of the study
8. Have been registered with a GP for at least the past 3 months and willing to allow a clinical investigator to discuss the volunteers medical history with their GP
9. For females only, using a reliable method of contraception (methods defined as one of; combined oral contraceptive pill, desogestrel-containing progesterone only pill (Cerazette), intra-uterine contraceptive device or system, injectable contraceptive or progesterone implant) from 14 days prior to the vaccination until 90 days after vaccination
10. For females only, willing to undergo urinary pregnancy tests on the day of screening, on the day of vaccination (prior to vaccination) and 28 and 90 days after vaccination
11. For males only, willing to use barrier contraception (male condoms) with every act of sexual intercourse until 28 days after the vaccination. The clinical site will provide condoms.
12. Agree to registration on a national database of trial volunteers to prevent over-volunteering (TOPS) which includes the taking of a photograph to be kept at the trial site

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 20

Key exclusion criteria
1. Prior receipt of a recombinant adenoviral-vectored vaccine
2. Participation in another research study involving an investigational product in the 30 days preceding enrolment, or planned enrolment during the study period
3. Receipt of a live attenuated vaccine within 60 days or other vaccine within 14 days of screening
4. Administration of immunoglobulins and/or any blood products within the three months preceding the planned administration of the vaccine candidate
5. History of allergic disease or reactions likely to be exacerbated by any component of the vaccine or a history of severe or multiple allergies to drugs or pharmaceutical agents
6. History of clinically significant contact dermatitis
7. Any history of severe local or general reaction to vaccination as defined as:
7.1. Local : extensive, indurated redness and swelling involving most of the antero-lateral thigh or the major circumference of the arm, not resolving within 72 hours
7.2. General : fever = 39.5°C within 48 hours, anaphylaxis, bronchospasm, laryngeal oedema, collapse, convulsions or encephalopathy within 48 hours
8. Females pregnancy, less than 12 weeks postpartum, lactating or willingness/intention to become pregnant during the study and for 3 months following vaccination
9. Seropositive for hepatitis B surface antigen (HBsAg) or Hepatitis C (antibodies to HCV)
10. Any history of Leishmaniasis or positive antibody response on the InBios leishmania strip test
11. Significant concern raised by GP in relation to participation
12. Any clinically significant abnormal finding on screening biochemistry or haematology blood tests or urinalysis
13. Any confirmed or suspected immunosuppressive or immunodeficient state, including HIV infection; asplenia; recurrent, severe infections and chronic (more than 14 days) immunosuppressant medication within the past 6 months (only mild to moderate topical steroids as listed in the BNF are allowed)
14. Any other significant disease, disorder or finding, which, in the opinion of a medically qualified Clinical Investigator, may either put the volunteer at risk because of participation in the study, or may influence the result of the study, or the volunteers ability to participate in the study
15. Unable to read and speak English to a fluency level adequate for the full comprehension of procedures required in participation and consent
16. Unlikely to comply with the study protocol

Date of first enrolment
16/04/2013

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Learning and Research Centre
York
United Kingdom
YO31 8HE

Sponsor information

Organisation
York Hospital HNS Trust (UK)

Sponsor details
Learning and Research Centre
Wigginton Road
York
England
United Kingdom
YO31 8HE

Sponsor type
Hospital/treatment centre

Website
http://www.york.nhs.uk/

Organisation
University of York

Sponsor details
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United Kingdom
YO10 5DD
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Sponsor type
University/education

Website
http://www.york.ac.uk/

Organisation
York Hospital

Sponsor details

Sponsor type
Not defined

Website
http://www.yorkhospitals.nhs.uk/our_hospitals/_the_york_hospital/

ROR
https://ror.org/0003zy991

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) Grant Codes: 085879

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/05/2017		Yes	No
HRA research summary			28/06/2023	No	No