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Research to improve economical anti-rabies treatment

Submission date	Recruitment status	[_] Prospectively registered
22/07/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/12/2012	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof David Warrell

Contact details
John Radcliffe Hospital
Nuffield Department of Clinical Medicine
Headington
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 220968
david.warrell@ndm.ox.ac.uk

Additional identifiers

Protocol serial number
065947

Study information

Scientific Title
A randomised comparative study of the immunogenicity of a modified intradermal post-exposure rabies vaccine regimen

Study objectives
To find a single economical post-exposure rabies vaccine regimen suitable for use with all vaccines currently recommended by the World Health Organisation (WHO), by testing the initial immunogenicity of a new variation of current intradermal post-exposure treatment regimens. Any new method must induce a rapid initial immune response, in comparison with control regimens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
After temporary recruitment problems, approval for the smaller study was received from the Oxfordshire Clinical Research Ethics Committee (ref: C01.078).

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rabies vaccine

Interventions
220 healthy volunteers in the UK between the ages of 18 and 50 years will be recruited and randomised into one of four treatment groups of 55 people each. The standard intramuscular rabies post-exposure vaccine regimen will be compared with two current economical intradermal regimens and a new improved intradermal regimen.

Unfortunately, recruitment was badly affected by a general anti vaccination sentiment in UK resulting from the media campaign against MMR. Our intention to recruit from the armed forces was thwarted by bad experiences with multiple vaccinations, in particular against anthrax, in preparation for the Iraq war. The funds for the trial ran out last year and while seeking an extension of the grant, recruitment was stopped temporarily. We have re-evaluated what can be achieved using internal funds and honorary staff, and have now restarted recruiting. The strategy has been changed to carry out a smaller study. The size is reduced by elimination of three of the seven study arms. The remaining groups will still provide data on the most important objectives, and may give results which could alter routine rabies post-exposure treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Rabies vaccine regimes

Primary outcome(s)
Blood samples are taken to measure the level of rabies virus-neutralising antibody by the Rabies antibody responses (RIFFIT) method. The serological results of the test regimen will be compared with those of control reference regimens of proven clinical efficacy.

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/07/2006

Eligibility

Key inclusion criteria
1. Healthy volunteers in Oxfordshire between the ages of 18 and 50 years, either sex
2. Have never had rabies vaccine before
3. Able to attend all appointments

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Any previous rabies immunisation
2. Treatment with human immunoglobulins or blood transfusion within the past three months
3. The use of immunosuppressive drugs
4. Pregnancy
5. Uncertainty about returning for appointments during the year
6. Chloroquine cannot be taken for two weeks prior to vaccination at day zero until two weeks after vaccination at day 90

Date of first enrolment
01/01/2005

Date of final enrolment
30/07/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 065947)

Results and Publications

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	23/04/2008		Yes	No