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Clinical trial of two new anti-snake venoms for the treatment of patients bitten by venomous snakes in Nigeria

Submission date	Recruitment status
13/01/2009	No longer recruiting
Registration date	**Overall study status**
18/02/2009	Completed
Last Edited	**Condition category**
30/12/2020	Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
EC003/05

Study information

Scientific Title
Pre-clinical and clinical assessment of new anti-venoms for the treatments of patients envenomed by the saw-scaled or carpet viper (Echis ocellatus) in northern Nigeria

Acronym
ECGECP

Study objectives
EchiTAb™ G and EchiTAb™ Plus have similar efficacy and safety profiles with South African Institute for Medical Research (SAIMR) anti-venom (Gold standard) in restoration of coagulation after envenomation from the bite of Echis ocellatus.

Please note that as of 11/02/10 the primary outcome field of this trial have been updated. Please view the relevant field for more details.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. National Agency for Food and Drug Adminstration and Control (NAFDAC), Nigeria, gave approval on the 12th February 2005
2. Gombe State Governmental Medical Research Ethical Committee gave approval on the 8th March 2005 (ref: MOH/ADM/S/909/V.I/11)

Study design
Randomised controlled double blind non-inferiority trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Snake bite

Interventions
EchiTAb™ Plus is produced by the Instituto Clodomiro Picado (ICP), University of Costa Rica in collaboration with the EchiTAb study group Nigeria/UK and Liverpool School of Tropical Medicine and University of Oxford. This is an equine trispecific anti-venom raised against the venoms of Nigerian E. ocellatus, Bitis arietans (puff adder) and Naja nigricollis (spitting cobra). These venoms were selected because, from a medical point of view, they are the three most important snake species in sub-Saharan Africa. The anti-venom is prepared by caprylic acid precipitation of non-IgG plasma proteins. Preclinical tests using WHO-approved methods showed these antivenoms to be as effective or almost as effective against E. ocellatus venom as the original ovine Fab fragment monospecific EchiTAb™. The final product is presented as a liquid in 10 ml vials with a 3 year expiry period. 30 ml EchiTAb™ Plus will be given to each participant.

EchiTAb™ G, which was developed and produced by EchiTAb study group Nigeria/UK, in collaboration with Micropharm Ltd UK and Liverpool School School of Tropical Medicine and Hygiene, is a purified IgG prepared by caprylic acid precipitation of non-IgG plasma proteins similar to the Costa Rican anti-venom described above. The final preparation is a liquid 10 ml vial with a 3-year expiry time. 10 ml EchiTAb™ G will be given to each participant.

Both anti-venoms are given through the intravenous route slowly (at the rate of 2 ml/minute). To ensure blinding however, sterile water is drawn into the syringe by the Hospital Pharmacist (who is not part of the research team) to making up to 40 ml of a mixture of anti-venom and sterile water. Once a patient has been enrolled into the study and allocated to one of the two treatment groups, 20-minute Whole Blood Clotting Time (20WBCT) test is done to establish coagulopathy. Once established, the anti-venom is given, six hours after which the 20WBCT is repeated to establish whether or not coagulation is restored. If restored, no anti-venom is given, but the same test is repeated 6-hourly for 48 hours, and the patient subsequently discharged if coagulation is sustained. However, in a situation where the blood during the 20WBCT after administration of anti-venom does not clot, a repeat dose of the anti-venom is given and the same process followed until coagulation is sustained for up to 48 hours. Note that immediately after administration of the anti-venom, observation is made for signs of early anaphylactic or pyrogenic reactions.

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
EchiTAb™ G anti-venom, EchiTAb™ Plus anti-venom, South African Institute for Medical Research (SAIMR) anti-venom

Primary outcome(s)
Current information as of 11/02/10:
Restoration of blood coagulability, measured 6 hours after the initial dose of antivenom is deemed the primary outcome and time point of main interest. Incoagulable blood, measured at baseline, is an eligibility criterion.
To ensure that restoration of blood coagulability at 6 hr is not transient followed by recurrent envenoming, it is also checked at 12, 18, 24 and 48 hours after the initial dose of antivenom.

Initial information at time of registration:
Blood coagulability, measured at baseline, 6, 12, 18, 24 and 48 hours after treatment

Key secondary outcome(s))
1. Anaphylactic reaction, measured immediately after treatment with anti-venom
2. Pyrogenic reaction, measured immediately after treatment with anti-venom
3. Late serum sickness, measured 2 weeks after discharge

Completion date
28/12/2008

Eligibility

Key inclusion criteria
Patients of both sexes and all ages bitten by snakes provided that:
1. They had incoagulable blood as defined by 20 minutes whole blood clotting time, indicative in this area of systemic envenoming by E. ocellatus
2. They have been bitten within the previous 72 hours
3. They or their relatives give informed consent to admission, treatment and investigation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
400

Key exclusion criteria
1. Patients who had received antisnake venom within the last 24 hours
2. Pregnant women
3. Patients with clinical features of severe envenoming (shock, massive bleeding, lateralising signs suggesting intracranial haemorrhage, etc.) who require urgent treatment with a large dose of anti-venom and resuscitation

Date of first enrolment
14/05/2005

Date of final enrolment
28/12/2008

Locations

Countries of recruitment
Nigeria

Study participating centre
Department of Community Medicine
Kano
Nigeria
700001

Sponsor information

Organisation
Federal Ministry of Health (Nigeria)

ROR
https://ror.org/02v6nd536

Funder(s)

Funder type
Government

Funder Name
Federal Ministry of Health (Nigeria)

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	27/07/2010	30/12/2020	Yes	No