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A phase II, randomised, double-blind, placebo-controlled, dose-finding, safety and tolerability trial of XY2405 as a treatment for traumatic brain injury

Submission date
25/04/2006

Registration date
12/05/2006

Last Edited
12/03/2010

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data
[_] Record updated in last year

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
N/A

Study information

Scientific Title

Acronym
BRAIN trial

Study objectives
This study aims to evaluate the safety of three different doses of XY2405 when used as a treatment for acute traumatic brain injury in order to inform dose selection for a phase III trial.

Please note that as of 26/09/2007 this trial record was updated by the PI. The end date of this trial was extended (the previous end date of this trial was 30/04/2008). The number of participants and trial recruitment countries (Estonia was added) have also been updated. Any changes to the trial have been noted under the date 26/09/2007.

Please note that as of 31/07/2008 the end date of this trial was stopped early and did not reach its full sample size. The actual end date of this trial was therefore 06/06/2008. The anticipated end date of this trial was 30/08/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received 20th December, 2007.

Study design
Randomised, parallel-groups, double-blind, placebo-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Traumatic brain injury

Interventions
XY2405 (anatibant) - a Bradykinin B2 receptor antagonist versus placebo

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
XY2405

Primary outcome(s)

To evaluate the safety of different doses of XY2405 when used as a treatment for acute traumatic brain injury in order to inform dose selection for a phase III trial

Key secondary outcome(s))
1. To assess the effect of XY2405 on mortality, morbidity and biomarkers of blood brain barrier dysfunction among patients with acute traumatic brain injury. Mortality will be assessed two weeks following the injury. In-hospital morbidity will be assessed two weeks post injury.
2. To assess pharmacokinetic (PK) profile in a larger population of patients

Completion date
06/06/2008

Reason abandoned (if study stopped)
Stopped early and didn't reach full sample size.

Eligibility

Key inclusion criteria
1. Age: legally adult, between 16 and 65 years, inclusive
2. Gender: male or non-pregnant female (no childbearing potential or negative pregnancy test)
3. Head trauma within eight hours to initiation of treatment with study drug
4.Glasgow Coma Scale Score of 12 or less
5. Computed tomography (CT) scan showing intracranial abnormality consistent with trauma
6. Consented in accordance with local legal requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with an extremely poor prognosis for survival based on clinical judgement
2. Known treatment with another investigational drug therapy within 30 days of injury

Date of first enrolment
01/11/2006

Date of final enrolment
06/06/2008

Locations

Countries of recruitment

United Kingdom

England

Belgium

Canada

Colombia

Czech Republic

Estonia

India

Romania

South Africa

Spain

Study participating centre
London School of Hygiene and Tropical Medicine
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
Xytis Pharmaceuticals Sàrl (Switzerland)

Funder(s)

Funder type
Industry

Funder Name
Xytis Pharmaceuticals Sàrl (UK)

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	03/12/2009		Yes	No