

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	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/05/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/03/2010	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2006

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

Age group

Adult

Sex

Both

Target number of participants

A total of 500 patients will be randomised (as of 26/09/2007 this has been updated to 400)

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**

Belgium

Canada

Colombia

Czech Republic

England

Estonia

India

Romania

South Africa

Spain

United Kingdom

Study participating centre

London School of Hygiene and Tropical Medicine

London

United Kingdom

WC1E 7HT

Sponsor information

Organisation

Xytis Pharmaceuticals Sàrl (Switzerland)

Sponsor details

4 Avenue Edouard Rod
Nyon
Switzerland
CH-1260

Sponsor type

Industry

Website

<http://www.xytis.com/pharma/>

Funder(s)

Funder type

Industry

Funder Name

Xytis Pharmaceuticals Sàrl (UK)

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	03/12/2009		Yes	No