

German trial of Acyclovir and Corticosteroids in Herpes-simplex-virus-Encephalitis

Submission date 23/08/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/09/2019	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.klinikum.uni-heidelberg.de/index.php?id=4223&L=en>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2005-003201-81

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

German trial of Acyclovir and Corticosteroids in Herpes-simplex-virus-Encephalitis

Acronym

GACHE

Study objectives

The GACHE trial aims to evaluate the effect on morbidity and mortality of early adjuvant corticosteroids (dexamethasone) in the treatment of adult patients with Herpes-Simplex-Virus-Encephalitis (HSVE).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Ethics Committee of the University of Heidelberg Medical Faculty on the 28th August 2006 (ref: AFmu-106/2006).

Study design

Multicentre, randomised, double-blind, placebo-controlled, parallel group clinical trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Herpes-Simplex-Virus-Encephalitis (HSVE)

Interventions

Treatment with acyclovir and adjuvant dexamethasone, as compared to treatment with acyclovir and placebo in adults with herpes-encephalitis.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Acyclovir and dexamethasone

Primary outcome measure

Binary functional outcome after six months measured by the mRS, a seven-point-scale zero to six. A mRS-score of three to six will be seen as an unfavourable outcome.

Secondary outcome measures

1. Mortality after six and 12 months
2. Functional outcome after six months measured by Glasgow Outcome Scale (GOS) and quality of life (EuroQol 5D)
3. Functional outcome after 12 months (mRS, GOS) and quality of life (EuroQol 5D)
4. Neuropsychological testing after six months, cranial Magnetic Resonance Imaging (MRI) findings after six months
5. Seizures up to day of discharge or at the latest at day 30, and after six and 12 months

Overall study start date

01/10/2006

Completion date

31/07/2011

Eligibility

Key inclusion criteria

1. Proven herpes-encephalitis (positive Herpes Simplex Virus-Deoxyribonucleic Acid-Polymerase Chain Reaction [HSV-DNA-PCR])
2. Aged between 18 and 85
3. Focal neurological signs not longer than five days prior to admission
4. Informed consent

Added as of 05/04/2007:

5. Women of childbearing potential: negative pregnancy testing in urine

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

372 patients, potential sample size extension up to 450 patients

Total final enrolment

41

Key exclusion criteria

1. History of hypersensitivity to corticosteroids
2. Systemic corticosteroid treatment within the last six months or at present time
3. Two fixed dilated pupils
4. Pre-event score modified Rankin Scale (mRS) more than two or Barthel Index less than 95
5. Pregnancy
6. Breast feeding women
7. Recent history of active tuberculosis or systemic fungal infection
8. Recent head trauma/neurosurgery/peptic ulcer disease
9. Life expectancy less than three years
10. Other serious illness that confound treatment assessment
11. Simultaneous participation in another clinical trial
12. Previous participation in another clinical trial in the last 30 days
13. Previous participation in this clinical trial

Added as of 05/04/2007:

14. Women of childbearing potential who are not using a highly effective birth control method
15. Acute viral infections other than HSVE (herpes zoster, poliomyelitis, chickenpox), Hepatitis B surface Antigen (HBsAg)-positive chronic active hepatitis, approximately eight weeks before to two weeks after prophylactic vaccination, lymphadenitis following Bacille Calmette Guérin (BCG) vaccination

Date of first enrolment

01/10/2006

Date of final enrolment

31/07/2011

Locations

Countries of recruitment

Austria

Germany

Netherlands

Study participating centre

Steinbacher Hohl 2-26

Frankfurt am Main

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Sponsor information

Organisation

University Hospital of Heidelberg (Germany)

Sponsor details

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Sponsor type

University/education

Website

<http://www.klinikum.uni-heidelberg.de/Neurologie-und-Poliklinik.600.0.html>

ROR

<https://ror.org/013czdx64>

Funder(s)**Funder type**

Government

Funder Name

German Aerospace Center (Deutsches Zentrum für Luft- und Raumfahrt e.V. [DLR]) (Germany)

Funder Name

Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung [BMBF]) (Germany) (ref: 01KG0504)

Alternative Name(s)

Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location
Germany

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?
Protocol article	protocol	29/10/2008	17/09/2019	Yes	No
Results article	results	01/12/2019	17/09/2019	Yes	No