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

Submission date	Recruitment status	[X] Prospectively registered
23/08/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/09/2019	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2005-003201-81

Protocol serial number
GFVT01026904 (GACHE)

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).

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
Germany
60488

Sponsor information

Organisation
University Hospital of Heidelberg (Germany)

ROR
https://ror.org/013czdx64

Funder(s)

Funder type
Government

Funder Name

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

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

Alternative Name(s)
Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

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	01/12/2019	17/09/2019	Yes	No
Protocol article	protocol	29/10/2008	17/09/2019	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes