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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).

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

## Primary study design
Interventional

## 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 |