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Intravenous dexamethasone versus oral glycerol versus placebo in reducing auditory sequelae of childhood bacterial meningitis

Submission date	Recruitment status	[ ] Prospectively registered
08/12/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/02/2010	Nervous System Diseases	

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
1

Study information

Scientific Title

Acronym
Estudio GLI

Study objectives
Oral glycerol (GLY) may be at least as efficaceous as parenteral dexamethasone (DXM) in reducing auditory and other sequealae caused be bacterial meningitis of childhood.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ministério da Saude, Comissão Nacional de Ética em Pesquisa - CONEP (ref: Parecer No. 1137 /2001, Registro CONEP 2339), approval date: Oct. 2, 2001.

Study design
Prospective randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Bacterial meningitis

Interventions
Adjuvant medication with intravenous DXM, oral GLY, both, or neither agent.

4 arms:
Arm 1: DXM + placebo (PLA)
Arm 2: DXM + GLY
Arm 3: GLY + PLA
Arm 4: PLA + PLA

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dexamethasone, glycerol

Primary outcome measure
1. Death
2. Severe neurological sequelae
3. Hearing impairment

Secondary outcome measures
Composite endpoints:
1. Severe neurological sequelae or death
2. Subanalysis on Hib meningitis with or without prior antimicrobials

Overall study start date
26/12/1996

Completion date
31/12/2003

Eligibility

Key inclusion criteria
Children at age two months to 16 years in whom bacterial meningitis was diagnosed and treated in the Institutions

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Months

Upper age limit
16 Years

Sex
Both

Target number of participants
704

Key exclusion criteria
1. Recent head injury
2. Previous neurosurgery
3. Neurological diseases

4. Immunosuppression
5. Known hearing impairment
6. More than one dose of parenteral anti-microbial

Date of first enrolment
26/12/1996

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
Argentina

Brazil

Dominican Republic

Ecuador

Finland

Paraguay

Venezuela

Study participating centre
HUCH Hospital for Children and Adolescents
Helsinki
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Sponsor information

Organisation
Alfred Kordelin Fund (Finland)

Sponsor details
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Sponsor type

Not defined

ROR
https://ror.org/0107h6s84

Funder(s)

Funder type
Industry

Funder Name
Alfred Kordelin, Päivikki and Sakari Sohlberg, and Sigfird Jusélius Funds (Finland)

Funder Name
GlaxoSmithKline company (in initial phase) (Finland)

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	15/11/2007		Yes	No
Results article	results	01/01/2009		Yes	No
Results article	results	01/01/2010		Yes	No