

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

Submission date 08/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/02/2010	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title

Acronym

Estudio GLI

Study objectives

Oral glycerol (GLY) may be at least as efficacious as parenteral dexamethasone (DXM) in reducing auditory and other sequelae caused by bacterial meningitis of childhood.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ministério da Saúde, 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

Study type(s)

Treatment

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(s)

1. Death
2. Severe neurological sequelae
3. Hearing impairment

Key secondary outcome(s))

Composite endpoints:

1. Severe neurological sequelae or death
2. Subanalysis on Hib meningitis with or without prior antimicrobials

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 months

Upper age limit

16 years

Sex

All

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

Finland

00029

Sponsor information

Organisation

Alfred Kordelin Fund (Finland)

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

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