Analysis of 12 year medical treatment in neonates with spina bifida in the Wilhelmina Children's Hospital

Published: 12-12-2006
Last updated: 21-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Neurological disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON30152

Source
ToetsingOnline

Brief title
Spina bifida and outcome

Condition

- Neurological disorders congenital

Synonym
spina bifida

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: K.F. Heinefonds te Utrecht

Intervention

Keyword: end-of-life decision, medical decision making, myelomeningocele, neonatal

Outcome measures

Primary outcome

1. What are the experiences of parents concerning the decision-making process

leading to the active termination of the life of their child?

2. Do the experiences of parents who agreed to the active termination of the

life of their child differ form the experieces of parents who did not agree?

3. What are the experiences of parents concerning the decision-making process

leading to a positive advise to start treatment?

Secondary outcome

none

Study description

Background summary

Between 1992 and 2004 214 neonates with spina bifida were referred to the Wilhemina Children's Hospital in Utrecht. When a neonate is admitted, all members of the spina bifida team perform physical examinations and additional examinations following a protocol during some days. An advise for treatment is proposed to the parents in a several meetings.
Sometimes a negative advise is given. When parents agree after a period of reflection, an active termination is proposed. When parents do not agree treatment is started.

In 1997 the report *Toetsing als Spiegel van de Medische Praktijk* by the Ministry of Welfare, Health and Cultural Affairs came out. The report contains recommendations concerning requirements of carefulness that are to be taken

into account when decisions about stopping or not starting treatment or end-of-life decisions are being made. These requirements form the theoretical basis for this study. However, they leave space for the own judgement of the physician and for contribution by the parents. The guidelines are not clear. There is a need for more knowledge about decision making by physicians and parents.

Study objective

By studying in which cases what decisions has been made we hope to get more insight into the interpretation of the requirements of the Ministry in everyday practise. Furthermore, it is important to know how all persons involved and especially the parents look back upon the procedure and decision-making in the Wilhelmina Children*s Hospital.

Study design

A descriptive study will be used to document the medical situation, the socio-economic status and the result of the decision-making process of all children (44) that were given a negative advise (regardless of the agreement of the parents) and of a sample of the children (108) given a positive advise. Also, the parents are interviewed in an structured manner.

Study burden and risks

We expect parents to relive a difficult period of their past life. By our high demands on the qualifications of the interviewer we tried to keep the emotional burden as low as possible. When parents get psychological problems after all, the study team will take care of the treatment of those problems.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

parents of neonates with spina bifida, born between 1992 and 2004 and treated by the spina bifida team in UMC Utrecht

Exclusion criteria

other malformations than spina bifda
and children with spina bifida sent to the hospital as a second opinion at an older age (> 2 months)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-09-2006
Enrollment:	152
Type:	Anticipated

Ethics review

Approved WMO Date:	12-12-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL12330.041.06