

Torticollis in infants due to suboccipital strain: a pilot study

Submission date 05/07/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/07/2021	Condition category Musculoskeletal 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

Contact name
Mrs Else Beth Haugen

Contact details
Akershus Universitetssykehus
Sykehusveien 27
Lørenskog
Norway
1478
+47 67 92 83 40
elsebeth.haugen@ahus.no

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2679035

Study information

Scientific Title

Torticollis in infants due to suboccipital strain: a pilot study

Study objectives

The movement patterns of the neck in infants with torticollis treated with manual therapy in addition to child physiotherapy is normalising more rapidly than in infants treated with child physiotherapy alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Regional Committee of Medicine Science Ethics, Southern Norway (Regional komite for medisinsk forskningsetikk Sor-Norge) on the 2nd May 2007 (ref: S-07104a).

Study design

A randomised, single blinded controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Torticollis in infancy

Interventions

Group 1: receives manual therapy once or twice in addition to child physiotherapy. Manual therapy will take place at the first visit, and then again in four weeks time if necessary.
Group 2: receives child physiotherapy only. Child physiotherapy will take place before, during and after the trial period. How often this takes place will be decided by what the child needs.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Each infant is videotaped three times during the study period of eight weeks. The films are assessed by three child physiotherapists and scored individually into five different categories due to the seriousness of the torticollis.

Primary and secondary outcomes will be measured at the first visit, after 2 weeks and at last after 8 weeks. The randomisation then ends and both groups can get manual therapy if it is needed.

Secondary outcome measures

1. Active range of movement of the neck
2. Compensations during active rotation of the neck
3. Passive range of movement of the neck (rotation, lateral and ventral flexion)
4. Signs of pain when passive range of movement is tested
5. Antigravity movement of the neck during lateral tilting of the infant
6. Anamnestic information
7. Questionnaire: this questionnaire is in Norwegian, and consists of seven questions with a Visual Analog Scale line

Primary and secondary outcomes will be measured at the first visit, after 2 weeks and at last after 8 weeks. The randomisation then ends and both groups can get manual therapy if it is needed.

Overall study start date

02/05/2007

Completion date

31/12/2007

Eligibility

Key inclusion criteria

1. Infants with torticollis, aged 3 - 6 months
2. Active and passive range of movement of the neck must be restricted

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Months

Upper age limit

6 Months

Sex

Both

Target number of participants

Total final enrolment

32

Key exclusion criteria

1. Serious pathology - somatic and cognitive
2. Syndromes
3. Intermittent torticollis

Date of first enrolment

02/05/2007

Date of final enrolment

31/12/2007

Locations**Countries of recruitment**

Norway

Study participating centre

Akershus Universitetssykehus

Lørenskog

Norway

1478

Sponsor information**Organisation**

Akershus University Hospital (Akershus Universitetssykehus) (Norway)

Sponsor details

Forskningsadministrativ enhet

Sykehusveien 27

Lørenskog

Norway

1478

+47 67 92 79 14

tone.kjefsoy@ahus.no

Sponsor type

Hospital/treatment centre

Website

<http://www.ahus.no/>

ROR

<https://ror.org/0331wat71>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Strategic Research Funds of Akershus University Hospital (Strategiske forskningsmidler ved Akershus Universitetssykehus) (Norway)

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		01/05/2011	15/07/2021	Yes	No