

# Torticollis in infants due to suboccipital strain: a pilot study

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

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## 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

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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?
<a href="#">Results article</a>		01/05/2011	15/07/2021	Yes	No