

# The Scandcleft project

<b>Submission date</b> 25/01/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/03/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/09/2021	<b>Condition category</b> Genetic Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Approximately one child in 500-600 is born with a cleft of the lip and/or palate. These arise in the womb when the different components of the lips, the upper jaw and the hard and soft palate fail to complete their growth. One-sided (or unilateral) clefts can include a complete gap in the lip, jaw, and palate. Even with modern surgery to close the cleft, affected children often require lengthy treatment into the late teens to optimise facial and dental appearance, speech, and hearing. The initial surgeries performed in the first year or so of life, are critical in determining the long term outcomes and the need for subsequent treatment. However, there is a great deal of uncertainty and controversy concerning the surgical timing and techniques that should be adopted. The purpose of this study is to compare the success of different surgical techniques for closing complete unilateral clefts of the lip and palate.

### Who can participate?

Infants attending cleft lip and palate centres in Denmark, Finland, Norway, Sweden, and the UK

### What does the study involve?

Participants are randomly allocated to one of four groups. Those in group 1 undergo lip and soft palate closure at 3-4 months of age and hard palate closure at 12 months/ Those in group 2 have similar treatment than those in group 1 – they just have their hard palate repair at 36 months. Those in group 3 undergo lip repair at 3-4 months and hard and soft palate closure at 12 months. Those in group 4 have their lip and hard palate repaired at 3-4 months and soft palate repaired at 12 months. Records for each group of participants is collected, which includes short term results of the surgery, the recovery period, the need for further surgery, longer term speech and language development, dental and jaw development, and nose/lip appearance.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

A total of 9 Cleft Lip and Palate/ Craniofacial Centres in Denmark, Finland, Norway, Sweden and the UK.

### When is the study starting and how long is it expected to run for?

September 1997 to September 2024

Who is funding the study?  
European Commission

Who is the main contact?  
Professor Gunvor Semb  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Gunvor Semb

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## Additional identifiers

## Study information

**Scientific Title**  
Randomised control trial of primary surgery for cleft lip and palate

**Study objectives**  
Null hypothesis that different surgical protocols for closure of complete unilateral cleft lip and palate do not produce different outcomes

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

1. Regional Committee for Medical Research Ethics, Norway, Oslo and Bergen (Regional Komite for Medisinsk Forskningsetikk), 29/08/1997, ref: S-971522
2. Research Committee at Karolinska Hospital, Sweden - Stockholm and Linkoping (Forskningskommitten vid Karolinska Sjukhuset), 31/10/1997, ref: 97-372
3. Gothenburg Regional Research Committee at the University of Gothenburg, Sweden (Göteborgs Regionala Forskningskommitten vid Göteborgs Universitet), 21/05/1997, ref: R257-97

4. Science Ethics Committee, Denmark- Copenhagen and Aarhus (Videnskabsetisk Komite), 13/10/1997, ref: 309/97
5. Helsinki University Hospital Ethics Committee ( HYKS Sairaala Eettinen Toimikunta), 04/09/1997
6. Local Research Ethics Committee, UK - Manchester, Salford & Trafford, June 1999, ref: 99/197
7. Queen's University of Belfast Ethics Committee, 08/06/1999, ref: 79/99

### **Study design**

Family of three RCTs

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Complete unilateral cleft lip and palate

### **Interventions**

One surgical protocol was defined to serve as a common method in each trial against which the established local protocols were compared. The common surgical protocol was lip and soft palate closure at 3-4 months and hard palate closure at 12 months.

Trial 1: compared this with only a variation in timing: hard palate repair at 36 months

Trial 2: compared this with lip repair at 3-4 months followed by hard and soft palate closure at 12 months

Trial 3: compared this with lip and hard palate repair at 3-4 months and soft palate repair at 12 months

The primary outcomes at age 5 were speech and dentofacial development, with a series of perioperative and longer term secondary outcomes.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

1. Speech and language at age 5 years, via blinded panel assessments using standardised audio /video recordings with regard to consonant proficiency and ratings of velopharyngeal competency and hypernasality
2. Dentofacial development at 5 years, via blinded panel ratings of dentofacial relationship represented by articulated plaster casts of the dentition using the Five Year Yardstick and Huddart-Bodenham Index

### **Key secondary outcome(s)**

1. Perioperative complications recorded by medical and nursing staff
2. Operation and hospitalisation time
3. Postoperative recovery and feeding recorded by medical and nursing staff
4. Speech at 12 and 18 months and 3 years
5. Symptomatic fistulae
6. Hearing

- 7. Burden of care
- 8. Parent satisfaction at age 5 years

**Completion date**

01/09/2024

## Eligibility

**Key inclusion criteria**

Caucasian patients born with non-syndromic unilateral complete cleft lip and palate. Patients with a soft tissue bridge (Simonart`s band) could be included as long as the width of the soft tissue bridge was not more than 5mm. The prevailing language of the country where recruited had to be spoken at home.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

All

**Total final enrolment**

429

**Key exclusion criteria**

1. Non-caucasian
2. Wide Simonart band
3. Prevailing local language not spoken at home

**Date of first enrolment**

01/09/1997

**Date of final enrolment**

11/11/2006

## Locations

**Countries of recruitment**

United Kingdom

England

Denmark

Finland

Norway

Sweden

**Study participating centre**  
**Copenhagen/Aarhus Cleft and Craniofacial Centre**  
Copenhagen  
Denmark  
2100

**Study participating centre**  
**Helsinki Cleft and Craniofacial Centre**  
Helsinki  
Finland  
00029 HUS

**Study participating centre**  
**Gothenburg Cleft and Craniofacial Centre**  
Gothenburg  
Sweden  
SE 405 30

**Study participating centre**  
**Linköping Cleft and Craniofacial Centre**  
Linköping  
Sweden  
S-581 85

**Study participating centre**  
**Stockholm Cleft and Craniofacial**  
Stockholm  
Sweden  
S-171 76

**Study participating centre**  
**Oslo Cleft and Craniofacial**  
Oslo  
Norway  
NO-0424

**Study participating centre**  
**Bergen Cleft and Craniofacial**  
Bergen  
Norway  
N-5009

**Study participating centre**  
**Manchester Cleft Centre**  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Royal Belfast Hospital for Sick Children**  
Belfast  
United Kingdom  
BT 12 6BE

## **Sponsor information**

**Organisation**  
University of Manchester

**ROR**  
<https://ror.org/027m9bs27>

**Organisation**  
Oslo University Hospital Rikshospitalet

## **Funder(s)**

**Funder type**  
Government

**Funder Name**

European Commission

### Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Data sharing statement to be made available at a later date

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2017		Yes	No
<a href="#">Results article</a>	results	01/02/2017		Yes	No
<a href="#">Results article</a>	results	01/02/2017		Yes	No
<a href="#">Results article</a>	results	01/02/2017		Yes	No
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<a href="#">Results article</a>	results	01/02/2017		Yes	No
<a href="#">Results article</a>	results	01/02/2017		Yes	No
<a href="#">Results article</a>	results	01/02/2017		Yes	No
<a href="#">Results article</a>	results	01/02/2017		Yes	No
<a href="#">Results article</a>	comparison of dental arch relationships and dental indices at 5, 8, and 10 years	03/09/2021	06/09/2021	Yes	No
<a href="#">Other publications</a>	analysis of baseline morphology	24/12/2020	29/12/2020	Yes	No