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The Scandcleft project

Submission date 25/01/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/03/2016	**Overall study status** Completed	
Last Edited 06/09/2021	**Condition category** Genetic Diseases	

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?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/09/1997

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

Age group
Child

Sex
Both

Target number of participants
450

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
Denmark

England

Finland

Norway

Sweden

United Kingdom

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

Sponsor details
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Philip.Eyres@manchester.ac.uk

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Organisation
Oslo University Hospital Rikshospitalet

Sponsor details
Sognsvannsveien 20
0372 Oslo
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Norway
0372 Oslo

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Ten manuscripts regarding age 5 outcomes and parent satisfaction will be submitted for journal publication in February 2016

Intention to publish date
29/02/2016

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?
Results article	results	01/02/2017		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/02/2017		Yes	No
	results	01/02			

Results article		/2017		Yes	No
Results article	results	01/02 /2017		Yes	No
Other publications	analysis of baseline morphology	24/12 /2020	29/12 /2020	Yes	No
Results article	comparison of dental arch relationships and dental indices at 5, 8, and 10 years	03/09 /2021	06/09 /2021	Yes	No