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Early restorative crown therapy in children and adolescents with amelogenesis imperfecta

Submission date
10/11/2010

Recruitment status
No longer recruiting

Registration date
26/01/2012

Overall study status
Completed

Last Edited
14/11/2016

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Amelogenesis imperfecta (AI) is a rare genetic disorder that affects the enamel of the teeth. It is caused by the malfunction of proteins that make up the enamel. The condition affects all or nearly all of the teeth in an equal way. The chances of anyone having the condition is dependent on where they live. 1 in 700 people in Sweden have AI, for example, compared to only 1 in 14,000 in the USA. The condition causes a number of problems for those afflicted; these include a lifelong need for dental treatment that is often painful and leads to fear of the dentist, teeth very sensitive to changes in temperature, the appearance of discoloured and misshapen teeth, teeth misalignment leading to an open bite, delayed tooth eruption in children, impacted teeth and pulp obliteration. AI can also affect a persons self-esteem, and results in a generally lower quality of life, a lesser chance than average of getting married and fewer children. Full-coverage, permanent ceramic crowns can be an effective way of treating the condition. The standard therapy is to treat younger patients by covering the surface of the tooth with plastic fillings, which can then be replaced by the permanent crowns once they have reached the age of 20-25 years. However, there is currently no scientific data to show at what age the permanent ceramic crowns should be fitted and it may be possible to do so earlier than at present. The aim of this study is to analyse the effects of treating younger patients with AI (i.e between 12-25 years) with permanent ceramic crowns. Two different types of crown are compared (Procera and Empress) with a view to answering the following questions:
1. Are there any differences in the ceramic crown treatment for patients with soft surface enamel disturbances compared to those with thin but hard enamel?
2. How do the two different types of ceramic crowns compare?
3. How frequently do complications occur if permanent crowns are fitted at an earlier age?
4. Does quality of life improve after crown therapy treatment?

Who can participate
Patients with AI aged between 12-25 years and referred to the pediatric dental clinic in Dalarna, Sweden.

What does the study involve?
Two types of ceramic crowns are compared: Procera and Empress. They are described as being similar in appearance and durability. A common method called split mouth is applied where all

the teeth on one side of the mouth is fitted with one type of crown, and all the teeth on the opposite side, the other type. The side allocated to be fitted with the first type of crown is selected randomly. The front teeth are all treated with the same (randomly selected) type of crown for cosmetic reasons.

What are the possible benefits and risks of participating?
Potential benefits include less teeth sensitivity, improved self-esteem and less mouth pain. Risks include an increase in tooth sensitivity, pulpal complications, porcelain fractures and the development of a visible cervical crown line as the young person gets older.

Where is the study run from?
Patients are treated at the pediatric dentistry specialist clinic in Falun. The scientific analysis is done at the Karolinska Institutet, Department of Dental Medicine, Sweden.

When is the study starting and how long is it expected to run for?
The study started in 2010 and closes to new patients after January 2012. Follow ups will continue to January 2014.

Who is funding the study?
The study is funded by the public dental health service, county of Dalarna, Center for clinical research in the county of Dalarna and American Dental Society of Sweden.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Early restorative crown therapy in children and adolescents with amelogenesis imperfecta: a prospective double-blind randomised controlled trial

Study objectives
Treatment with Procera crown therapy with zirkonia inner couping cemented with Rely X ARC cement results in a better clinical outcome compared to E-MAX crowns with zirkonia inner couping cemented with Rely X ARC in children and adolescents with amelogenesis imperfecta

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Board, Uppsala University, Sweden, 16/07/2008, ref: 2008/108

Study design
Prospective single-centre double-blind randomised controlled trial

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 below to request a patient information sheet [Swedish]

Health condition(s) or problem(s) studied
Amelogenesis imperfecta

Interventions
Treatment with Procera crown therapy with zirkonia inner couping cemented with Rely X ARC cement or E-MAX crowns with zirkonia inner couping cemented with Rely X ARC in children and adolescents with amelogenesis imperfecta

Intervention Type

Procedure/Surgery

Primary outcome measure
1. Quality of restorations after 1 month, 1 year and a 2-year observation period according to Ryge & De Vinzenci (1983)
2. Sensitivity, measured using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain) at baseline, 1 month and 2 years

Secondary outcome measures
1. Dental caries according to Amarante et al (1998)
2. Gingivitis and periodontitis according to Nyman and Linde (2003)
3. Apical status according to Örstavik (1986)

Overall study start date
01/01/2009

Completion date
31/12/2013

Eligibility

Key inclusion criteria
Children and adolescents with amelogenesis imperfecta, 6 to 25 years of age, referred for oral rehabilitation

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
Amelogenesis imperfecta in combination with syndromes including mental retardation

Date of first enrolment
01/01/2009

Date of final enrolment

31/12/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet
Huddinge
Sweden
SE-14104

Sponsor information

Organisation
Centre for Clinical Reserach, Public Dental Service Dalarna (Sweden)

Sponsor details
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Sponsor type
Government

Website
http://www.ltdalarna.se/templates/Base____25.aspx

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Center for Clinical Research, Public Dental Service Dalarna (Sweden)

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	results	01/11/2014		Yes	No
Results article	results	01/08/2015		Yes	No
Results article	results	10/12/2015		Yes	No
Results article	results	30/06/2016		Yes	No