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A randomised controlled trial in primary care of a novel method of using preformed metal crowns to manage decay in primary molar teeth: the Hall technique

Submission date
12/06/2007

Recruitment status
No longer recruiting

Registration date
05/07/2007

Overall study status
Completed

Last Edited
21/09/2011

Condition category
Oral Health

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Nicola Innes

Contact details
Level 9
Dental Hospital and School
University of Dundee
Park Place
Dundee
United Kingdom
DD1 4HN
+44 (0)1382 635992
n.p.innes@dundee.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
It has long been known that the carious process can be arrested. There has been growing awareness that it may not be necessary to remove as much carious dental tissue as was previously thought. By simply changing the environment within which the caries is progressing, and making it unfavourable for the micro-organisms involved, the number and diversity of micro-organisms can be dramatically reduced. This means that the carious disease process may be slowed down, perhaps halted, and possibly even reversed. The Hall technique makes use of a simplified, potentially more acceptable method of placing Preformed Metal Crowns (PMCs). It is used to seal the carious lesion into the tooth, making the environment unfavourable by limiting the lesions access to nutrients. This should slow, or even arrest the progress of the carious lesion through the tooth. In addition, by avoiding the use of Local Anaesthesia (LA) and caries removal, it is possible that the Hall technique might be more acceptable than standard restorative techniques to children, their parents and General Dental Practitioners (GDPs). The randomised controlled clinical trial reported in this thesis was designed to investigate these hypotheses.

The overall aim of the research project was to determine whether the Hall technique offered benefits over current practice to restore carious primary molar teeth in general dental practice in Tayside. Specifically, the potential benefits of interest were:
1. Acceptability of the procedure
2. Long-term pulpal health
3. Longevity of the restoration, and
4. Costs of the procedures together with their follow-up maintenance

This led to the following null hypotheses being tested through the clinical trial:
1. After a minimum of 23 months, there is no difference in the incidence of signs and symptoms of pulpal disease between teeth restored with control restorations and those with PMCs fitted using the Hall technique
2. After a minimum of 23 months, there is no difference in longevity of restorations between control restorations and PMCs fitted using the Hall technique
3. Children, their carers and GDPs have no preference between the Hall technique and control restorations placed by their GDPs, and
4. After a minimum of 23 months, there is no difference in the cost of provision and maintenance of the control restorations and Hall PMCs to the service provider

Information on the pilot trial at http://www.dundee.ac.uk/tuith/Articles/rt03.htm

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the Tayside Committee on Medical Research Ethics (ref: 108/00).

Study design
Randomised controlled trial, split-mouth design.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dental decay

Interventions
A preformed metal (stainless steel) crown will be placed on one of the pairs of carious primary molar teeth of the child. The other molar tooth will be given a standard treatment.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following outcomes will be assessed at least 23 months after the placement of the crown:
1. Absence of signs/symptoms of pulpal pathology
2. Resoration failure requiring intervention

Secondary outcome measures
1. Acceptability of the intervention technique
2. Cost effectiveness

Overall study start date
01/07/2001

Completion date
01/07/2011

Eligibility

Key inclusion criteria

Children aged 4 to 9 years of age with pairs of carious primary molar teeth, matched for arch, tooth type and extent of caries.

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
Medical contra-indications, i.e., children at risk of infective endocarditis.

Date of first enrolment
01/07/2001

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Level 9
Dundee
United Kingdom
DD1 4HN

Sponsor information

Organisation
Chief Scientist Office (UK)

Sponsor details
Scottish Executive Health Department
St Andrew's House
Regent Road
Edinburgh
United Kingdom
EH1 3DG
+44 (0)131 244 2246
karen.ford@scotland.gsi.gov.uk

Sponsor type
Government

Website
http://www.sehd.scot.nhs.uk/cso/

ROR
https://ror.org/01bw7zm61

Funder(s)

Funder type
Government

Funder Name
Chief Scientists Office (UK) - Research Training Fellowship Award, Scottish Executive

Funder Name
3M ESPE (USA)

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	01/12/2011		Yes	No