ISRCTN90779069 https://doi.org/10.1186/ISRCTN90779069

The effect of extracting badly decayed baby teeth from young underweight Filipino children on the childrens weight and height

Submission date
22/12/2011

Recruitment status
No longer recruiting

Registration date
25/01/2012

Overall study status
Completed

Last Edited
21/06/2013

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
In many low- and middle-income countries, the proportion of untreated dental decay of the baby teeth in young children is high. In a national study in the Philippines, dental decay was universal in 6-year-old children. On average they had over eight baby teeth that were either decayed, or had been extracted or filled because of decay. in over 84% of cases the decay was advanced and had reached the pulp causing infection or abscesses in bone and tissues outside the tooth - this is what severely decayed teeth means. Poor oral health in children is linked to underweight and failure to thrive. In a previous Philippines National Oral Health Survey children needing multiple extractions of severely decayed teeth had significantly lower body weights than children with no decay. Complete dental rehabilitation of underweight children with severe dental decay has been shown to be linked to an increased rate of weight gain that may have been related to eliminating dental pain and infection that negatively affected childrens ability to eat and sleep. The objective of this study was to measure if extraction of severely decayed baby teeth affected weight and height in underweight preschool Filipino children, using a randomised controlled trial design (children were randomly allocated to one of two groups).

Who can participate?
All children included in the study were attending day care centres in villages in the Provinces of Cagayan de Oro and Misamis Oriental, Northern Mindanao, Philippines. Children aged between 4 years and 6 months to 5 years and 8 months participated. They were all underweight and had severe dental decay in one or more baby teeth. All children were tested for active tuberculosis infection. Children testing positively were not included, as were children with other medical conditions and infections.

What does the study involve?
Screening visit: All carers, in selected Barangays, were invited to bring their children to a screening session. Trained interviewers obtained basic information about the children such as date of birth, general health and oral problems using a structured interview. Childrens weight and height were measured and their mouths examined. Underweight children meeting the inclusion criteria were invited to join the study.

Treatment visit: Immediately prior to treatment weight and height were again recorded and a blood sample taken to test for anaemia. All severely decayed teeth were extracted using local anaesthesia and other less seriously decayed teeth were treated with silver-diamine-fluoride which slows progression of decay. The childrens carers were interviewed to provide information on the impact that dental problems had on their childrens daily lives.

Follow-up visit 1: Four months later Group B children received the identical treatment as Group A children had received four months earlier. Group A children had weight and height measured and their carers were interviewed.

Follow-up visit 2: All children had weight and height measured and their carers were interviewed as previously. Both Group A and Group B children also had a second blood sample taken to assess anaemia.

What are the possible benefits and risks in taking part?
The children benefit from receiving dental treatment that they would not otherwise be able to access. The children will have greatly reduced dental pain and be able to eat and sleep better. Carers too will enjoy improved peace-of-mind knowing that their children have greatly reduced pain, eat and sleep better.
The risks of high quality dental extractions in young children under local anaesthesia are rare and very minimal, should they occur. Many thousands of dental extractions are carried out around the world each year with very few complications. Complications are infrequent and easily dealt with, resulting in no lasting harm.

Where is the study run from?
Locally in Cagayan de Oro

When is the study and how long is it expected to run for?
The study started in May 2009 and ended in April 2010.

Who is funding the study?
This study was supported by a grant from FDI World Dental-Education.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Testing the effects of tooth extraction in preschool underweight Filipino children with severe dental decay followed by increased velocity of weight gain and improvement in oral health related quality of life

Study objectives
Seriously decayed teeth cause pain and make eating and sleeping difficult. A lack of sleep and poor eating causes, among other things, young children to be underweight and not grow properly. It can have serious lifelong effects on their mental and physical development. This study measures the effects on the subsequent growth (height) and weight of young children after they had their seriously decayed (those with pulpal infection) baby teeth extracted.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kinaadman Research Center, Xavier University (Philippines), 4 April 2008

Study design
Randomized wait - list control parallel stratified cluster clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dental caries, dental decay

Interventions
Group A: Intervention group
Group B : Wait-list control

Immediately prior to treatment weight and height were recorded and a blood sample taken to test for anaemia. The intervention consisted of extracting all pulpally involved teeth under local anaesthesia, and painting other carious teeth with silver-diamine-fluoride to arrest the decay. The childrens carers were interviewed to provide information on the impact that dental problems had on their childrens daily lives.

Both Groups A and B received the same treatment the only difference was that Group B received treatment 4 months after Group A.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Changes in height, weight and quality of life scores in study subjects

Key secondary outcome(s))
1. Changes in Z-scores of height and weight between Group A and Group B
2. Changes in eating, sleeping, and other quality of life impairments
3. Changes in haemoglobin levels

Completion date
30/03/2010

Eligibility

Key inclusion criteria
1. Severe dental decay i.e. one or more teeth with dental pulp involvement irrespective of number of teeth decayed
2. Body weight below normal (underweight) according to age, using National Center for Health Statistics (NCHS) reference standards
3. Children aged between 4 years and 6 months to 5 years and 8 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit
5 years

Sex
All

Key exclusion criteria

1. Children with high caries levels, but no pulpal involvement
2. Children with systemic medical conditions and infectious diseases (e.g. active tuberculosis infection)

Date of first enrolment
01/05/2009

Date of final enrolment
30/03/2010

Locations

Countries of recruitment
United Kingdom

England

Philippines

Study participating centre
Research Department of Epidemiology and Public Health
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
World Dental Federation (Fédération Dentaire Internationale) (FDI) (Switzerland)

ROR
https://ror.org/049htfh25

Funder(s)

Funder type
Research organisation

Funder Name
World Dental Federation (Fédération Dentaire Internationale) (FDI) (Switzerland)

Results and Publications

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	31/08/2012		Yes	No
Results article	results	03/06/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes