ISRCTN58467151 https://doi.org/10.1186/ISRCTN58467151

The effectiveness of an internet based computer database for data collection in a randomised controlled trial to evaluate immediate extirpation of necrotic pulp tissue and placement of Ledermix® in avulsed and replanted teeth in comparison to the current recommendations

Submission date 30/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/10/2005	**Overall study status** Completed	
Last Edited 21/12/2011	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2, 9-12-04

Study information

Scientific Title

Study objectives
This is a multi-centre randomised controlled trial to compare the effectiveness of Ledermix® and Ultracal XS® on the type of healing (favourable or unfavourable) following tooth avulsion and replantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Tooth avulsion and replantation

Interventions

Pulp extirpation as early as possible (Day 010) following tooth avulsion and placement of Ledermix® versus pulp extirpation at Day 710 and placement of Ultracal XS® (non setting calcium hydroxide).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ledermix®, Ultracal XS®

Primary outcome measure
To compare the effect of these two root canal pastes on the periodontal healing and consequent tooth survival.

Secondary outcome measures
To evaluate the effectiveness of a web based computer database for data collection in a multi-centred randomised controlled trial for two types of treatment for avulsion injuries.

Overall study start date
20/07/2005

Completion date
30/09/2008

Eligibility

Key inclusion criteria
There are two ways to be accepted onto the trial; acute and delayed presentation to the specialist unit.

Inclusion criteria for acute presentation are:
1. Patients who have avulsed a tooth that has been replanted and are under the age of 16 years
2. The tooth has completed root development with or without an open apex (as these teeth have no chance of pulpal regeneration)
3. With no more than 20 minutes dry extra-alveolar time
4. A maximum total time of one hour has elapsed with the tooth being kept outside the mouth in milk or other storage media and a maximum of 20 minutes being kept in dry conditions
5. With no previous endodontic treatment carried out
6. The patient presents to the specialist unit within ten days following the injury (this ensures that the patient has a chance of randomly being entered into one or other treatment group)

Inclusion criteria for delayed presentation:
1. Where replantation has been carried out away from a specialist centre and is performed within the guidelines of the International Association of Dental Traumatology (2003)
2. Details can be obtained from the dentist who provided this treatment (e.g. extra alveolar time, extra alveolar medium, dry time, surface contamination, antibiotics, etc.)
3. Meets the same inclusion criteria as listed above for acute presentation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
Not fulfilling the inclusion criteria

Date of first enrolment
20/07/2005

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Paediatric Dentistry
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Industry

Funder Name
Blackwell Supplies (purchase of equipment and free materials)

Funder Name
Optident (free materials)

Funder Name
Medartis (free materials)

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	01/08/2011		Yes	No