

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/12/2011	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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**Organisation**

University of Leeds (UK)

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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