ISRCTN46246539 https://doi.org/10.1186/ISRCTN46246539

Exposure of palatal canines: cover-plate vs periodontal dressing

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/04/2018	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Upper (maxillary) canines erupt at approximately 11-12 years of age. Occasionally, these teeth erupt into the wrong position or do not erupt at all and become impacted. The upper canine can become displaced towards the cheek (buccally) or into the roof of the mouth (palatally). Approximately 1-2% of the population is affected. Upper canines become impacted palatally in 85% of cases and buccally in 15%.
Management of established canine impactions often requires surgical and orthodontic intervention if the canine is to be correctly positioned within the dental arch.
This study compares the use of a coverplate (CP) versus a sutured periodontal dressing (PD) following surgical exposure of palatal canine teeth.

Who can participate?
Patients taken consecutively from the orthodontic waiting list at Queen Alexandra Hospital fulfilling the following criteria:
1. Age 12 20
2. Requiring exposure of a palatally impacted canine(s)
3. Requiring general anaesthesia for exposure

What does the study involve?
Patients will be randomly allocated to one of two treatments: placement of a coverplate after exposure of a palatally impacted canine which is removed approximately 1 week after exposure; or suturing a periodontal dressing over the exposed canine which is removed approximately 1 week following exposure.

Patients will be seen again 7-10 days after the exposure of the tooth, when the cover-plate or the dressing will be removed. Instructions will be given on how to keep the area clean.

What are the possible benefits and risks of participating?
The results of this study may help us treat future patients in a more efficient manner.
One possible disadvantage is that the treatment involving a cover-plate requires one extra visit 1 week before surgery to be able to make the cover-plate.

Where is the study run from?
The study was carried out in the Orthodontic Department, Queen Alexandra Hospital, Portsmouth (UK).

When is the study starting and how long is it expected to run for?
The study took place between October 2005 and October 2007.

Who is funding the study?
Portsmouth NHS Research and Development Consortium (UK)

Who is the main contact?
Dr Sirisha Ponduri
sirishaponduri@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Sirisha Ponduri

Contact details
Maxillofacial Department
Cosham
Portsmouth
United Kingdom
P06 3LY
+44 07815 130576
sirishaponduri@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0187173586

Study information

Scientific Title
Exposure of palatal canines: cover-plate vs periodontal dressing - A randomised clinical trial

Study objectives

The aims and objectives of this project is to compare the use of a cover-plate with the use of a sutured periodontal dressing following surgical exposure of the palatally impacted canine to see if one form of treatment is better than the other.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Isle of Wight, Portsmouth & SE Hampshire REC

Study design
Single-centre randomised controlled trial

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
Palatally impacted canine(s)

Interventions
1. Placement of a coverplate after exposure of a palatally impacted canine which is removed approximately 1 week after exposure
2. Suturing a periodontal dressing over the exposed canine which is removed approximately 1 week following exposure

The patient will be randomised to one of the two treatments (detailed above). Patients in each group then have a different treatment and these are compared.

So each participant will either have a cover-plate following surgery or the dressing. They will be seen again 7-10 days after the exposure of the tooth, when the cover-plate or the dressing will be removed. Instructions will be given on how to keep the area clean.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Exposure successful (re-exposure required?)
2. Was the coverplate/periodontal dressing in situ until the review appointment.
3. Patient comfort (visual analogue scale)

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/10/2005

Completion date
01/10/2007

Eligibility

Key inclusion criteria
1. Age 12 20
2. Requiring exposure of a palatally impacted canine(s)
3. Requiring general anaesthesia for exposure

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
100 participants (50 in each group).

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
11/10/2005

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
United Kingdom

Study participating centre

Maxillofacial Department
Portsmouth
United Kingdom
P06 3LY

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Portsmouth NHS Research and Development Consortium (UK)

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