

# Exposure of palatal canines: cover-plate vs periodontal dressing

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>29/09/2006   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>29/09/2006 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>30/04/2018       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Sirisha Ponduri

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## Additional identifiers

### Protocol serial number

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

## **Primary study design**

Interventional

## **Study design**

Single-centre randomised controlled trial

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

Not provided at time of registration

## **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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**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

**Funder(s)****Funder type**

Government

**Funder Name**

Portsmouth NHS Research and Development Consortium (UK)

**Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration