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An investigation of two methods of orthodontic space closure: nickel titanium versus stainless steel springs

Submission date
21/01/2013

Recruitment status
No longer recruiting

Registration date
29/01/2013

Overall study status
Completed

Last Edited
23/05/2016

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 this study, we intend to determine whether stainless steel springs are as effective as Nickel Titanium (NiTi) coil springs in orthodontic space closure during orthodontic treatment. If we can show that stainless steel springs work as effectively in terms of the rate of space closure, this will be an important finding with respect to orthodontic care and health care expenditure. The aims of this study were to: Compare the rate of orthodontic space closure between NiTi coil springs and stainless steel springs during fixed appliance treatment. Compare the cost effectiveness of NiTi coil springs and stainless steel springs in orthodontic space closure.

Who can participate?
Patients currently receiving orthodontic treatment in Countess of Chester Hospital and University of Manchester Dental Hospital.

What does the study involve?
In general, patients currently receiving orthodontic treatment who require orthodontic space closure between the first permanent molar and canine are suitable for this trial. All subjects who are eligible for inclusion will be interviewed and the purpose of trial will be outlined in written information sheets. Once consent is obtained, the patient will be randomly allocated to receive the stainless steel or nickel titanium spring as part of our routine space closing treatment. An impression of their teeth will be taken for study records at the start and completion of this trial. Apart from these, all participants will undertake the same routine treatment, as other non-trial patient would have. At the end of the trial, an examiner will take measurements of initial distance of space to be closed and after completion of space closure to determine the rate of space closure for each type of spring.

What are the possible benefits and risks of participating?
The possible benefits are rapid orthodontic space closure and shorter treatment time.
There are no significant risks or burdens for participants apart from the additional 5-10minutes during treatment time to undertake 2 sets of teeth impressions (study moulds) before and after the study trial commence

Where is the study run from?
This trial has been set up in Orthodontic Department, Countess of Chester Hospital and University of Manchester Dental Hospital.

When is the study starting and how long is it expected to run for?
This trial started in April 2011 and ran for one year until April 2012. However this trial may extend beyond this to collect, analyze and publish the data.

Who is funding the study?
There was no cost involved in purchasing these springs, as they were already available in the clinic. However, indemnity for this trial as has been provided by The University of Manchester.

Who is the main contact?
Dr Noraina Norman, norainanorman@gmail.com
Dr Stephen Chadwick, steve.chadwick@coch.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Stephen Chadwick

Contact details
Countess of Chester Hospital NHS Foundation Trust
Oral Surgery and Orthodontic Department
Liverpool Road
Chester
United Kingdom
CH2 1UL
-
steve.chadwick@coch.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Nickel titanium versus stainless steel springs: a randomized clinical trial of two methods of orthodontic space closure

Study objectives
Nickel titanium (NiTi) coil spring and stainless steel springs are commonly used to close space in between teeth in brace treatment. However, we do not know which of these two springs is faster at closing gaps. The purpose of this study is to find out which orthodontic spring closes gaps the fastest, therefore shortening treatment time.

The null hypothesis is that there is no difference in the rate of orthodontic space closure between patients treated with NiTi coil springs or stainless steel springs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS/HSC Research and Development North West 3 (Liverpool East) Research Ethics Committee 10 February 2011, (Reference: 10/H1002/71) for both sites of this study.

Study design
Prospective two-centred randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Rapid orthodontic space closure

Interventions
The intervention group will be allocated the stainless steel springs to close the space, whereas the control group will be allocated the nickel titanium coil springs.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

The rate of space closure in millimetres per month (4 weeks) in any quadrant requiring orthodontic space closure. Study record was taken at the start and conclusion of space closure period.

Secondary outcome measures
1. Treatment time that is required to close the space
2. To compare the cost effectiveness between the two groups of springs

Overall study start date
01/04/2011

Completion date
01/04/2012

Eligibility

Key inclusion criteria
1. Patients currently undergoing orthodontic brace treatment. We intend to include patients who are currently undergoing fixed appliance (brace) therapy regardless of age or sex. Although that, most orthodontic patients are adolescents between 12-17 year old.
2. Patients who require space closure between the canine and the first permanent molar
3. Informed written consent was obtained from the patient or the guardian/parent

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Patients who decline to take part in the study
2. Patients who cannot be given brace treatment due to poor oral hygiene

Date of first enrolment
01/04/2011

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Countess of Chester Hospital NHS Foundation Trust
Chester
United Kingdom
CH2 1UL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
c/o Dr Karen Shaw
Head of Research Office
Christie Building
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
University/education

Funder Name
University of Manchester (UK)

Alternative Name(s)

The University of Manchester, University of Manchester UK, University of Manchester in United Kingdom, UoM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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:	01/09/2016		Yes	No