ISRCTN80447398 https://doi.org/10.1186/ISRCTN80447398

Comparison between twin-block and forsus functional appliances

Submission date
09/07/2013

Recruitment status
No longer recruiting

Registration date
26/07/2013

Overall study status
Completed

Last Edited
12/08/2020

Condition category
Oral Health

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Sticking out front teeth is a common dental feature in the UK. It affects 20% of the white population. It affects the oral health and related quality of life in the adolescent population. Children who have upper front teeth sticking out are more susceptible to dental trauma or injury. Current evidence also suggests that they can be an easy target for being bullied at school. Sticking out front teeth can be corrected by seeking treatment from your local orthodontist. Usually, this is done by wearing a functional brace that maximises the potential growth of the lower jaw in order to keep up with the growth of the upper jaw. A functional brace works best on patients who are growing, thus the best time to treat this is when they are undergoing their pubertal growth spurt at the age of 12 years old for females and 14 years old for males. To date, functional braces could be classified into two broad categories: either a fixed functional appliance which is glued onto the teeth or a removable functional appliance. Research suggests that the most popular removable functional appliance in the UK is the twin-block appliance, whereas for the fixed functional appliance it is less clear. There are quite a few fixed functional appliances on the market. One that appears to work comparatively well is the Forsus fatigue resistant device (FRD). Both types of appliance work effectively. However, it is not certain which is more effective at reducing the horizontal gaps between the upper and lower front teeth. Hence, this study aims to answer this question.

Who can participate?
Adolescents with sticking out front teeth aged 12 to 14

What does the study involve?
Participants are randomly allocated to either the Forsus FRD group or the twin-block group. They need to wear the functional appliance for about 9 months (6 months full time and 3 months part time). They then need to wear a glued-on train track brace for a further 20 months. The total treatment would be for about 30 months. All patients are seen once every 6 to 8 weeks. At the end of each phase, they have an X-ray of their jaw (radiographs) taken. It is important to stress that there are no additional X-ray exposures required. The participants' general dental practitioners are informed regarding their involvement in the study. Participants also need to complete a questionnaire for feedback on the functional appliances.

What are the possible benefits and risks of participating?
There is a possibility that treatment with Forsus Functional appliance may lead to a shorter overall treatment time. However, there is no evidence to support this. The child's participation in this study would help to find out if this is the case. There are no anticipated risks involved with the participation in this study. The use of the appliances and visits required would be same whether or not the child is involved in the study.

Where is the study run from?
The study will be carried out at two orthodontic departments of the Northwest region, namely Stepping Hill Hospital at Stockport and University of South Manchester Hospital at Wythenshawe (UK)

When is the study starting and how long is it expected to run for?
September 2013 to August 2015

Who is funding the study?
Stockport NHS Foundation Trust (UK)

Who is the main contact?
Dr Maria McNally
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Contact information

Type(s)
Scientific

Contact name
Dr Maria McNally

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison between twin-block appliance and Forsus™ fatigue resistant device in treating class II division I malocclusion: a randomised controlled trial

Study objectives
Twin-block removable functional appliance and Forsus™ Fatigue Resistant Device do not have any difference with regards to treatment duration, quality of dento-occlusal outcome, breakages and patient discomfort in treating Class II Div I malocclusion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Will be seeking with the local ethics committee in August 2013 - pending

Study design
Two-centre randomised clinical controlled 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Sticking out upper front teeth is a variation of normal occlusion which is commonly associated with bullying, teasing and risk of trauma to the dentition. Treatment is aimed to improving the occlusal outcome and patients' self-esteem

Interventions
All subjects who are eligible for inclusion will be interviewed and the purpose of the trial will be outlined. Patients will be given information leaflets on their first visit as well as a detailed explanation of the trial and they are required to provide us feedback on whether they are willing to participate in this trial. If they are, informed consent will be obtained and the operator will contact the central trial coordinator to provide details of subject. The subject will then be randomly allocated, stratifying for operator and gender, to either Twin-block appliance or Forsus FRD appliance. Patients will be treated according to the treatment protocols as outlined without any additional appointments for the sake of the trial. In addition, the following data will be collected from patients notes:
1. Number of attendances, including failed & cancelled appointments

2. Overall treatment duration
3. Frequency of appliance breakages, if any

Patients will also be required to fill in the Smiles Better questionnaires which will inform how the appliances will affect them as part of the qualitative assessment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Treatment duration. All outcomes will be measured at baseline (T1) and at the end of active treatment (T2). Records will be taken at these time points which will include: study models, radiographs and pictures.

Secondary outcome measures
1. Quality of the dento-occlusal outcome measured on study models
2. Pancherz analysis on cephalograms
3. Qualitative assessment using questionnaires on how the appliances affect them
4. Breakages
5. Cost

Overall study start date
01/09/2013

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Patients with Class II Division I malocclusion
2. Overjet > 6mm
3. All permanent teeth erupted except second and third molars
4. Aged 10-15 years old

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
64

Key exclusion criteria
1. Possible orthognathic treatment is required or there is a strong indication it will be required in the future
2. Presence of any craniofacial anomaly / syndrome
3. Maxillary mandibular plane angle of more than 37˚
4. Previous orthodontic treatment and/or premolar extraction
5. Hypoplastic permanent teeth first molars
6. Hypodontia of any tooth in any quadrant excluding third molars
7. Subjects involved in any other orthodontic trials
8. Inadequate oral hygiene

Date of first enrolment
01/09/2013

Date of final enrolment
31/08/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Stockport NHS Foundation Trust
Stockport
United Kingdom
SK2 7JE

Sponsor information

Organisation
Stockport NHS Foundation Trust (UK)

Sponsor details
c/o Jan Smith
F 08 Pinewood House Stepping Hill Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220rp185

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Stockport NHS Foundation Trust (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