

Chewing gum and orthodontic pain

Submission date 29/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/03/2017	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

Contact name

Dr A J Ireland

Contact details

University of Bristol
Division of Child Dental Health
Bristol
United Kingdom
BS8 1TH

Additional identifiers

EudraCT/CTIS number

2008-005522-36

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

6631

Study information

Scientific Title

Chewing gum and orthodontic pain: a randomised interventional and observational cohort study

Study objectives

The null hypothesis in this intention to treat study is that there is no difference between the use of ibuprofen and sugar-free chewing gum in the relief of orthodontic pain in the 3 days following the fitting and then subsequent adjustment of orthodontic fixed appliances. The secondary outcome measure is bracket or wire failure. In addition patient anxiety will be measured following brace fitting and subsequent adjustment as anxiety may affect the perception of pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North Somerset and South Bristol Research Ethics Committee, 26/11/2008, ref: 08/H0106/139

Study design

Randomised interventional and observational cohort study

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

Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Oral & Dental

Interventions

The control is ibuprofen and the intervention is sugar-free chewing gum.
Study entry: single randomisation only

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Ibuprofen

Primary outcome measure

Pain

Secondary outcome measures

1. Bond failures, measured following fitting and then following first adjustment
2. Anxiety

Overall study start date

19/10/2009

Completion date

01/04/2011

Eligibility**Key inclusion criteria**

1. Aged 12 - 16 years, either sex
2. Upper and lower fixed orthodontic appliances

Participant type(s)

Patient

Age group

Child

Lower age limit

12 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

Planned Sample Size: 1000; UK Sample Size: 1000

Key exclusion criteria

Asthmatic with reaction to aspirin or non-steroidal anti-inflammatory drugs (NSAIDs)

Date of first enrolment

19/10/2009

Date of final enrolment

01/04/2011

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University of Bristol

Bristol

United Kingdom

BS8 1TH

Sponsor information

Organisation

Royal United Hospital Bath NHS Trust (UK)

Sponsor details

Combe Park

Bath

England

United Kingdom

BA1 3NG

Sponsor type

Hospital/treatment centre

Website

<http://www.ruh.nhs.uk/>

ROR

<https://ror.org/058x7dy48>

Funder(s)

Funder type

Research organisation

Funder Name

British Orthodontic Society (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016		Yes	No
Results article	results	01/03/2017		Yes	No
HRA research summary			28/06/2023	No	No