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Chewing gum and orthodontic pain

Submission date 29/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/04/2010	**Overall study status** Completed	
Last Edited 02/03/2017	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-005522-36

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised interventional and observational cohort study

Study type(s)
Treatment

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(s)
Pain

Key secondary outcome(s)
1. Bond failures, measured following fitting and then following first adjustment
2. Anxiety

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
16 Years

Sex
All

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
United Kingdom

England

Study participating centre
University of Bristol
Bristol
United Kingdom
BS8 1TH

Sponsor information

Organisation
Royal United Hospital Bath NHS Trust (UK)

ROR
https://ror.org/058x7dy48

Funder(s)

Funder type
Research organisation

Funder Name
British Orthodontic Society (UK)

Results and Publications

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