

# Chewing gum and orthodontic pain

<b>Submission date</b> 29/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/03/2017	<b>Condition category</b> 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**  
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## 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?
<a href="#">Results article</a>	results	01/08/2016		Yes	No
<a href="#">Results article</a>	results	01/03/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No