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A randomised trial of gum chewing to reduce post-operative ileus

Submission date	Recruitment status	[_] Prospectively registered
12/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/04/2017	Digestive System	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Charlotte Atkinson

Contact details
University of Bristol
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7704

Study information

Scientific Title

A multicentre randomised interventional trial of chewing sugar-free gum post-operatively to reduce hospital stay and post-operative ileus

Study hypothesis
The primary hypothesis to be addressed is that chewing sugar-free gum post-operatively reduces the length of hospital stay via a reduction in the duration of ileus. Other hypotheses to be addressed are that chewing sugar-free gum post-operatively reduces co-morbidities associated with ileus (including clinical outcomes such as vomiting, infection, and anastomotic dehiscence), improves quality of life and reduces costs of care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Somerset and South Bristol REC, 29/05/2009, ref: 09/H0106/37

Study design
Multicentre randomised interventional 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

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

Interventions
200 patients will be randomised to receive usual care plus gum and 200 will be randomised to receive usual care only. Patients in the gum chewing arm will be asked to chew gum for at least 10 minutes four times a day for five days (or until discharge, whichever comes first).

Follow-up length: 3 months
Study entry: single randomisation only

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Length of hospital stay, calculated from date of operation to date of discharge.

Secondary outcome measures
1. Vomiting, measured during days 1 - 5 post-operation
2. Infection, measured during days 1 - 5 post-operation
3. Anastomotic dehiscence, measured during days 1 - 5 post-operation
4. Quality of life, measured during days 1 - 5 post-operation, and at 6 and 12 weeks post-operation
5. Costs of care, measured during days 1 - 5 post-operation, and at 6 and 12 weeks post-operation

Overall study start date
01/04/2009

Overall study end date
31/03/2012

Eligibility

Participant inclusion criteria
We will include a wide range of patients (aged greater than 18 years, either sex) to ensure that the findings of this study will be broadly applicable.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 400; UK sample size: 400

Participant exclusion criteria
1. Less than 18 years of age
2. Patients with Crohn's disease (as they may have markedly different nutritional needs and recoveries to most patients undergoing large bowel resection)
3. Emergency cases (non-gastrointestinal [GI] surgeons may do emergency surgery and pre-operative consent may not be possible)
4. Women who are pregnant or lactating

Recruitment start date

01/04/2009

Recruitment end date
31/03/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
Bristol
United Kingdom
BS1 2LY

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

Sponsor details
Research and Development
Upper Maudlin Street
Bristol
England
United Kingdom
BS2 8AE

Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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	01/07/2016		Yes	No