

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

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/04/2017	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 objectives

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

Health condition(s) or problem(s) studied

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

Completion date

31/03/2012

Eligibility

Key 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

Key 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

Date of first enrolment

01/04/2009

Date of final enrolment

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