ISRCTN20301599 https://doi.org/10.1186/ISRCTN20301599

POMX (Post Operative Morbidity): randomized controlled trial of chewing gum to reduce postoperative morbidity in elective orthopaedic surgery

Submission date	Recruitment status	[_] Prospectively registered
29/09/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/09/2015	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gareth Ackland

Contact details
Wolfson Institute for Biomedical Research
Gower Street
London
United Kingdom
WC1E 6BT
-
g.ackland@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10666

Study information

Scientific Title
POMX (Post Operative Morbidity): randomized controlled trial of chewing gum to reduce postoperative morbidity in elective orthopaedic surgery

Acronym
POM-X

Study objectives
Complications following surgery are an important cause of morbidity (illness) and mortality (death). When these complications occur within 30 days of major surgery, long term survival is reduced.

The return of gut movement after elective surgery is important to prevent nausea, vomiting, and abdominal discomfort. Under some circumstances this gut movement is reduced which can lead to delays in oral intake and delayed discharge from hospital. Gastrointestinal dysfunction after surgery is associated with morbidity in other body systems. Chewing-gum is considered a form of 'sham feed' e.g. an imitation of food ingestion. 'Sham-feeding' can help facilitate gut motility by the activation of gastrointestinal hormones.

The POM-X trial is designed to examine if the act of chewing gum following orthopaedic surgery can reduce the incidence of complications postoperatively.

Understanding this mechanism may help us to understand why some patients sustain complications after surgery.

This will allow future clinical care to be guided by an understanding of why these complications arise and allow early detection, treatment and avoidance of postoperative morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/H0722/3

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Oral and Gastrointestinal, Generic Health Relevance and Cross Cutting Themes; Subtopic: Oral and Gastrointestinal (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Gastrointestinal, Surgery

Interventions
Clinical assessment, including examination, electrocardiogram (ECG), basic physiological observations

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2011

Completion date
01/09/2012

Eligibility

Key inclusion criteria
Patients undergoing elective orthopaedic hip and knee arthroplasty procedures and meet the following criteria:
1. American Society of Anaesthesiologists risk grade 14
2. Age > 40 years
3. Have received a general anaesthetic with/without peripheral nerve block

Target Gender: Male & Female; Upper Age Limit 90 years ; Lower Age Limit 30 years

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
Planned Sample Size: 106; UK Sample Size: 106

Key exclusion criteria
1. Refusal of consent
2. Preoperative nasogastric feeding
3. Gastrostomy feeding
4. Preoperative impaired swallowing

Date of first enrolment
01/09/2011

Date of final enrolment
01/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wolfson Institute for Biomedical Research
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
University College London (UK)

Sponsor details
Institute of Ophthalmology
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
University/education

Funder Name
Academy of Medical Sciences

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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	01/11/2015		Yes	No