

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

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

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

Protocol serial number

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Wolfson Institute for Biomedical Research

London

United Kingdom

WC1E 6BT

Sponsor information

Organisation

University College London (UK)

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

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015		Yes	No