

Peri-operative Implementation Study Evaluation

Submission date 22/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/11/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/01/2013	Condition category Surgery	<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
1247/3737

Study information

Scientific Title

Peri-operative Implementation Study Evaluation: Implementing evidence into practice

Acronym

PolSE

Study objectives

What is the most effective implementation strategy for the uptake of evidence-based recommendations about peri-operative fasting?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The South East Research Ethics Committee approved on the 20th of April 2006 (ref: 06MRE01/20)

Study design

Pragmatic randomised trial, with time series and embedded process evaluation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Peri-operative fasting - in elective surgical patients - general surgery, gynaecological and orthopaedics

Interventions

Participating trusts were randomly allocated to one of three implementation strategies (6 trusts in two arms and 7 in one) on the basis of the prestudy sample size calculations the study had 80% power to detect an effect size of 2 (a difference of 4 hours).

1. Standard dissemination
2. Standard dissemination + web-based education resources + opinion leader
3. Standard dissemination + Plan-Do-Study-Act

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Duration of fluid and food fast - from commencement of food fast to induction of anaesthesia and nil by mouth to induction of anaesthesia.

Secondary outcome measures

1. Patient's experiences of fasting
 - 1.1. Qualitative interviews (pre-intervention 35, post-intervention 35)
 - 1.2. Questionnaire (pre intervention 1069, post intervention 1215)
2. Practitioner's experiences of implementing changes to practice
 - 2.1. Interviews with change agents and site contacts (pre intervention 28, post intervention 24)
 - 2.2. Focus groups with staff (5 post intervention)
 - 2.3. Learning Organisation Survey (pre intervention 758, post intervention 318)

Overall study start date

16/01/2006

Completion date

01/06/2009

Eligibility

Key inclusion criteria

1. Sites
19 acute hospital trusts across the 4 countries of the UK; England (15), Scotland (2), Wales (1), Northern Ireland (1)
2. Patients:
 - 2.1. Patients over the age of 18
 - 2.2. Patients undergoing elective general, orthopaedic or gynaecological surgery
 - 2.3. Patients who could provide informed consent to participate

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

19 Trusts (1575 inpatients assessed pre-intervention, 1930 patients assessed post-intervention)

Key exclusion criteria

1. Patients under the age of 18
2. Patients who are critically ill, had major surgery, in pain or suffering from any other discomfort
3. Emergency or trauma patients because we wish to look at routine fasting regimes
4. Patients who are cognitively impaired

Date of first enrolment

16/01/2006

Date of final enrolment

01/06/2009

Locations**Countries of recruitment**

United Kingdom

Wales

Study participating centre

School of Healthcare Sciences

Bangor

United Kingdom

LL57 2EF

Sponsor information**Organisation**

University of Warwick (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/01a77tt86>

Funder(s)

Funder type

Government

Funder Name

The Health Foundation (UK) - as part of their Engaging with Quality Initiative

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	30/08/2012		Yes	No