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Peri-operative Implementation Study Evaluation

Submission date 22/10/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/11/2010	**Overall study status** Completed	
Last Edited 21/01/2013	**Condition category** Surgery	

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
PoISE

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
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Sponsor information

Organisation
University of Warwick (UK)

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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