

Perioperative Analgesia for Knee Arthroplasty (PAKA) - a pilot randomised trial

Submission date 18/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/06/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/05/2014	Condition category Musculoskeletal Diseases	<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
PAKA/PROTOCOL/V002

Study information

Scientific Title

Acronym

PAKA

Study objectives

Peri-articular knee infiltration with Levobupivacaine 150mg, Morphine 10mg & Ketorolac 30mg reduces postoperative pain following primary total knee replacement compared with the current standard treatment of femoral nerve blockade

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Midlands Research Ethics Committee, REC Number: 10/H1208/37
Protocol number: PAKA/PROTOCOL/001 30 July 2010

Study design

Pilot single centre standard of care controlled trial double blinded pragmatic randomised trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Musculoskeletal, total knee arthroplasty, analgesia

Interventions

Femoral nerve block using 30ml of Levobupivacaine 0.25% versus Peri-articular infiltration of multimodal agents consisting of 150mg of Levobupivacaine, 10mg Morphine and 30mg Ketorolac diluted in 0.9% saline to make a volume of 100ml

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

1. Levobupivacaine 2. Morphine 3. Ketorolac

Primary outcome measure

Visual Analogue Scale at 18 hours post operation

Secondary outcome measures

Serum Levobupivacaine levels pre & post retransfusion

1. Functional assessment:

1.1. Straight leg raise

1.2. Mobility assessed bed to chair 18 & 48 hours post operatively

2. Oxford Knee Score 6 weeks post operatively

Overall study start date

01/01/2010

Completion date

31/12/2010

Eligibility

Key inclusion criteria

All patients undergoing an elective primary unilateral total knee replacement (TKA) under the care of an orthopaedic consultant at University Hospitals Coventry and Warwickshire NHS Trust

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

46

Key exclusion criteria

1. Cognitive impairment, unable to complete questionnaire

2. Patients who lack capacity under the Mental Capacity Act 2005

3. Patients with pre-operative history of neurological abnormality in the ipsilateral leg e.g. history of stroke, neurogenic pain or previous nerve injury

4. Patients having spinal anaesthesia

5. Patients with specific contraindication to the analgesic agents used: Morphine, Ketorolac, Levobupivacaine

Date of first enrolment

01/01/2010

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospitals Coventry & Warwickshire

Coventry

United Kingdom

CV2 2DX

Sponsor information

Organisation

University of Warwick (UK)

Sponsor details

c/o Peter Hedges

Research Support Services

University House

Coventry

England

United Kingdom

CV4 8UW

Sponsor type

University/education

Website

<http://www2.warwick.ac.uk/>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Astra Tech (UK)

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	01/12/2012		Yes	No
HRA research summary			28/06/2023	No	No