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

Submission date	Recruitment status	[ ] Prospectively registered
18/01/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/06/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/05/2014	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PAKA/PROTOCOL/V002

Study information

Scientific Title

Acronym

PAKA

Study objectives
Peri-articular knee infiltration with Levobupivicaine 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

Primary study design
Interventional

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

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Muskuloskeletal, total knee arthroplasty, analgesia

Interventions
Femoral nerve block using 30ml of Levobupivicaine 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. Levobupivicaine 2. Morphine 3. Ketorolac

Primary outcome(s)
Visual Analogue Scale at 18 hours post operation

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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 neruological abnormality in the ipsilateral leg e.g. history of stroke, neurogenic pain or previous nerve injury
4. Patients having spinal aneasthesia
5. Patients with specific contraindication to the analgesic agents used: Morphine, Ketorolac, Levobupivicaine

Date of first enrolment
01/01/2010

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Coventry & Warwickshire
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University of Warwick (UK)

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Industry

Funder Name
Astra Tech (UK)

Results and Publications

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