ISRCTN87161129 https://doi.org/10.1186/ISRCTN87161129

Warning Time and Patient Centred Goals with Transdermal Oxybutynin

Submission date	Recruitment status	[X] Prospectively registered
08/11/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/11/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/12/2011	Urological and Genital Diseases	

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
2005-005009-41

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EUDRACT 2005-005009-41

Study information

Scientific Title

Acronym
WTPCGTO

Study objectives
Transdermal oxybutynin reduces urinary warning time, and helps patients achieve their goals for treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending from King's College Hospital Research Ethics Committee

Study design
Double blind randomised controlled trial (RCT)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Overactive bladder

Interventions
Transdermal Oxybutynin or Placebo Patch

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Oxybutynin

Primary outcome measure
Achievement of goals score

Secondary outcome measures
1. Change in King's Health Questionnaire (KHQ) scores (by domain and total)
2. Change in mean, median and minimum warning time
3. Compliance with medication
4. Change in episodes of urgency/urge incontinence
5. Change in frequency/nocturia
Outcomes assessed by 3 day bladder diaries incorporating Patients Perception of Intensity of Urgency Scale (PPIUS)

Overall study start date
01/12/2005

Completion date
01/12/2007

Eligibility

Key inclusion criteria
At study entry:
1. Female patient aged ≥18
2. Written informed consent obtained
3. Patient is willing and able to complete the frequency volume chart (FVC) and questionnaires correctly
4. Symptoms of overactive bladder (frequency/urge/urge incontinence) for ≥3 months AND/OR previously demonstrated detrusor overactivity (DO) at urodynamics

At randomisation:
1. At least three episodes of urgency or urge incontinence on FVC over 3 days
2. At least frequency ≥8 on FVC over 3 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
96

Key exclusion criteria
At study entry:
1. History of allergy to oxybutynin or any of the ingredients of Kentera
2. History of allergy from medical tape or transdermal skin patch
3. Pregnancy, intention to become pregnant during study period, unreliable contraception

despite being sexually active, breast feeding
4. Urodynamic proven mixed incontinence
5. Voiding difficulties (flow rate <15 ml/s, or post void residual >50 ml)
6. Patient with indwelling catheter or practicing clean intermittent self-catheterisation (CISC)
7. Evidence of current urinary tract infection (UTI) or bladder stone or malignancy
8. Uncontrolled narrow angle glaucoma, myasthenia gravis, gastric or urinary retention, renal impairment or dialysis, moderate or severe hepatic impairment, chronic intestinal disease (including ulcerative colitis and gastrointestinal obstruction), megacolon, diabetic neuropathy, oesophageal inflammation (hiatus hernia, gastrooesophageal reflux), Parkinsons disease, or other significant clinical condition (at the discretion of the investigator)
9. Other specific medications: anticholinergics, antispasmodics, anti-parkinsonian, tricyclics, tetracyclics, duloxetine, antihistamines, antiemetics, diuretics, neuroleptics, type I antiarrythmics, opioids, alpha-antagonists, CYP3A4 inhibitors or inducers, any other bladder medication

At randomisation:
Failure to complete FVC according to instructions

Date of first enrolment
01/12/2005

Date of final enrolment
01/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
8 Devonshire Place
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W1G 6HP

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Prof Linda Cardozo
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England
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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
UCB Pharma (UK) - an investigator initiated study, meaning that investigators will 'own' the data, but UCB Pharma are funding on the assumption that the publication of the results will be of commercial benefit to them.

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	01/01/2011		Yes	No
Results article	results	01/05/2011		Yes	No
Results article	results	01/07/2011		Yes	No