ISRCTN03265047 https://doi.org/10.1186/ISRCTN03265047

A prospective, randomised, open, crossover patient preference study comparing oral immediate release and transdermal oxybutynin in overactive bladder patients

Submission date
31/01/2007

Recruitment status
Stopped

Registration date
22/03/2007

Overall study status
Stopped

Last Edited
30/07/2009

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
2006-001-Oxy-OAB-Skin-Oxy

Study information

Scientific Title

Acronym
Oxy-OAB-Skin-Oxy

Study objectives
The primary endpoint is treatment preference of subjects who will be asked at the end of the 2nd treatment period. The preference will be checked for its plausibility in an end-of-period satisfaction rating (6 = very satisfied, 0 = very dissatisfied). Treatment satisfaction will be assessed at the end of each period of the cross over. The total score on the satisfaction visual analog scale of the two treatment periods will be compared to express preference.

Ethics approval required
Old ethics approval format

Ethics approval(s)
In progress as of 2 February 2007

Study design
Prospective, randomised, open, 2 x 6 - week crossover, single-centre subject preference trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Subjects with overactive bladder (OAB)

Interventions
As of 29/07/09 the status of this trial was updated to 'stopped' due to poor recruitment. The decsion to terminate the trial was made on 25/11/2008, the date of last patient out (LPO) was on 17/07/2009

Test product: Kentera™ TDS 3,9 mg/24h, transdermal patch vs Reference therapy: Oxybutynin ratiopharm® 5 mg, tablets

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary efficacy endpoint will be the personal preference of the subject after both treatment phases. The preference will be checked for its plausibility in an end-of-period satisfaction rating (total of scores of final list of questions: 6 = very satisfied, 0 = very dissatisfied)

Secondary outcome measures
1. Cognitive abilities during treatment with orally administered Oxybutynin versus transdermal administration of Oxybutynin measured by CNS tests (Trail Making Test and Wechsler Memorial Scale-Revised)
2. Quality of life assessed with King´s Health Questionnaire
3. Severity of urinary incontinence episodes estimated in pad test at V1, V3, V4 and V6
4. Reports of adverse event (AE)/serious adverse event (SAE) in terms of severity and frequency
5. Frequency of micturition assessed in a 3 day diary in every treatment period
6. Urinary incontinence episodes assessed in a 3 day diary in every treatment period
7. Degree of severity of incontinence episodes estimated in Sandvik Index and documented at subject visits
8. Urgency frequency assessed in a 3 day diary in every treatment period
9. Treatment satisfaction will be assessed with a satisfaction questionnaire at the end of each treatment period

Overall study start date
01/03/2007

Completion date
01/12/2007

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Subjects meeting all of the following criteria will be considered for admission to the trial:
1. Male or female (18 80 years) suffering from OverActive Bladder (OAB)
2. Symptoms of OAB as defined by:
a. Urgency frequency ≥7 /week
b. Urinary urgency incontinence (> 7 UIE/week)
c. Urodynamically proven detrusor instability
3. Women must be surgically sterile, be postmenopausal or must agree to use effective contraception during treatment phases (i.e. contraceptions with a failure ratio of < 1%/ year are

implants, injection preparations, combined oral contraceptives, intrauterine device [e.g. hormone spiral] or vasectomy of the partner)
4. Negative urine pregnancy test for women capable of child-bearing within 24 hours before administration of the first dose medication at V1
5. Signed and dated informed consent of the subject must be available before start of any specific trial procedures
6. Ability of subject to understand character and individual consequences of clinical trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
It is planned to enroll 80 patients in the trial.

Key exclusion criteria
Subjects presenting with any of the following criteria will not be included in the trial:
1. Pregnancy and lactation
2. History of hypersensitivity to the investigational medicinal product or to any drug with similar chemical structure or to any excipient present in the pharmaceutical form of the investigational medicinal product
3. Subjects with significant urinary obstruction as measured during cystometry (e.g. prostatic hyperplasia, stricture of urethra), severe gastro-intestinal condition (e.g. toxic megacolon, severe ulcerative colitis, intestinal atony, bowel obstruction), myasthenia gravis or uncontrolled narrow-angle glaucoma
4. Refractory to antimuscarine treatment: Subjects having experienced no benefit from previous treatment with oral or transdermal oxybutynin
5. Subjects with hiatus hernia and reflux oesophagitis
6. Subjects with acute prostatitis
7. Subjects with urinary frequency or nocturia due to cardiac or renal insufficiency and without urgency
8. Subjects with tachyarrhythmia (pulse > 100/min)
9. Subjects with Parkinsons`s disease or Alzheimer`s disease or other cerebral diseases
10. Subjects with cognitive impairment, not able to understand content and aim of the trial
11. Medical or psychological condition that would not permit completion of the trial or signing of informed consent
12. Participation in other clinical trials and observation period of competing trials, respectively
13. Subjects who have previously been enrolled in the trial

Date of first enrolment
01/03/2007

Date of final enrolment

01/12/2007

Locations

Countries of recruitment
Germany

Study participating centre
Johannes Gutenberg-Universität Mainz
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Sponsor information

Organisation
Johannes Gutenberg-Universität Mainz, Fachbereich Medizin (Germany)

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Sponsor type
University/education

ROR
https://ror.org/023b0x485

Funder(s)

Funder type
Industry

Funder Name
UCB Farchim S.A. (Switzerland)

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