

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

<b>Submission date</b> 31/01/2007	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/03/2007	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/07/2009	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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 decision 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  $\geq 7$  /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` 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