Trial Description

Title

Noninterventional study on the administration of Spasmex® 45 mg coated tablets in elderly female and male patients suffering from symptoms of urge in daily urological practice - a noninterventional study with epidemiological aspects

Trial Acronym

NIS-056

URL of the trial

[---]*

Brief Summary in Lay Language

In the course of this study the routine use of the registered drug Spasmex 45 mg coated tablets for the indication of overactive bladder will be documented for scientific purposes. Elderly (≥ 65 years of age) male and female patients will be enrolled in the study, who visit a urological practice due to symptoms of overactive bladder, and who receive prescription for Spasmex 45 mg coated tablets following routine diagnosis by the treating physician.
The aims of the study is to determine:
- the extent of anticholinergic drug burden with potential cognitive impairment
- the extent of morbidity
- efficacy and tolerability of the drug used
- divisibility of the coated tablet into three parts.

Brief Summary in Scientific Language

Symptoms of an overactive bladder (OAB) (urgency, frequency and/or urge incontinence) are highly prevalent, with an increasing frequency in old age (Milsom et al. 2001). OAB affects the quality of life through to social isolation and depression (Griebling 2013). Multi-medication and additionally metabolites with anticholinergic effects may cause adverse reactions such as delirium, falls, cognitive impairment (Ancelin et al. 2006, Fox et al. 2011), and as a result lead to loss of independence (Pasina et al. 2013, Lertxundi et al. 2013), and to further deterioration of the patient's health status. Treatment with quarternary anticholinergic drugs, which are largely free of central nervous system effects, might be an approach for effective treatment of OAB without increasing the anticholinergic burden of the patients.
The described study with patients suffering from urge-symptoms will be divided into three parts:
a) an epidemiological survey
i. to determine the anticholinergic burden caused by drugs using the ACBS score and
ii. to determine and quantify the morbidity using the CIRS-G score.
b) a prospective investigation of efficacy and tolerabilty of Spasmex® 45mg coated tablets
c) a survey on the divisibility of Spasmex® 45mg coated tablets.

Organizational Data

- DRKS-ID: **DRKS00007109**
- Date of Registration in DRKS: **2014/10/29**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2014-343-f-S , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

Secondary IDs

Health condition or Problem studied

- MedDRA: **LLT,10059617:overactive bladder**
- ICD10: **N32.8 - Other specified disorders of bladder**

Interventions/Observational Groups

- Arm 1: **There is only one treatment arm. There are 3 visits per patient. The period of time between the visits corresponds to the general practice. A period of time of at least 10 days between the visits is recommended.**
  It will be recorded:
  1. Demographic data on visit 1
  2. Symptoms of overactiv bladder on visit 1, 2, and 3
  3. Morbidity using the CIRS-G questionnaire on visit 1
  4. Medicinal pre-treatment on visit 1
  5. Comedication with anticholinergic burden using the ACBS scale on visit 1, 2 and 3
  6. Additional relevant comedication on visit 1, 2 and 3
  7. Documentation of the therapy regimen
  8. Questioning of physician and patient regarding efficacy and tolerability on visit 2 and 3
  9. Questioning of patient regarding the divisibility of the coated tablet on visit 3
  10. Questioning of patient regarding adverse events on visit 2 and 3.
  11. Documentation of further treatment

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**

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- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

a) to determine the anticholinergic burden caused by drugs using the total score of Anticholinergic Cognitive Burden Scale (ACBS) on visit 1, 2 and 3
b) to determine and quantify the morbidity using the Cumulative Illness Rating Scale for Geriatrics (CIRS-G) on visit 1
c) to detemine the efficacy using the following parameters:
- number of micturitions per day (on visit 1, 2 and 3)
- intensity of urgency (on visit 1, 2 and 3)
- incontinence episodes (on visit 1, 2 and 3)
- overall assessment of efficacy by patient and by physician (on visit 2 and 3)
d) to determine the divisibility of the coated tablets using an ordinal scale (on visit 3)
e) overall assessment of tolerability by patient and by physician (on visit 2 and 3)
f) documentation of side effects (on visit 2 and 3)
A period of time of at least 10 days between the visits is recommended.

Secondary Outcome

See Primary outcome. In this noninterventional study there are no primary or secondary endpoints. All variables will be evaluated descriptively. No hypothesis will be tested, no comparison of different populations will be done.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Leipzig**

- Doctor's Practice **Augsburg**
- Doctor's Practice **Berlin**
- Doctor's Practice **Bottrop**
- Doctor's Practice **Brackenheim**
- Doctor's Practice **Burghausen**
- Doctor's Practice **Darmstadt**
- Doctor's Practice **Dillenburg**
- Doctor's Practice **Dossenheim**
- Doctor's Practice **Dresden**
- Doctor's Practice **Hamburg**
- Doctor's Practice **Heilbronn**
- Doctor's Practice **Köln**
- Doctor's Practice **Lengerich**
- Doctor's Practice **Ludwigshafen am Rhein**
- Doctor's Practice **Magdeburg**
- Doctor's Practice **Marburg**
- Doctor's Practice **Markkleeberg**
- Doctor's Practice **Neunkirchen**
- Doctor's Practice **Pößneck**
- Doctor's Practice **Reutlingen**
- Doctor's Practice **Schwelm**
- Doctor's Practice **Senftenberg**
- Doctor's Practice **Sinsheim**
- Doctor's Practice **Ahrensburg**
- Doctor's Practice **Alzenau**
- Doctor's Practice **Annaberg-Buchholz**
- Doctor's Practice **Bad Doberan**
- Doctor's Practice **Bad Nauheim**
- Doctor's Practice **Bad Zwischenahn**
- Doctor's Practice **Bamberg**
- Doctor's Practice **Bergkamen**
- Doctor's Practice **Bielefeld**

- Doctor's Practice **Bocholt**
- Doctor's Practice **Bochum**
- Doctor's Practice **Chemnitz**
- Doctor's Practice **Dinslaken**
- Doctor's Practice **Dortmund**
- Doctor's Practice **Düsseldorf**
- Doctor's Practice **Ebersberg**
- Doctor's Practice **Eilenburg**
- Doctor's Practice **Erfurt**
- Doctor's Practice **Essen**
- Doctor's Practice **Flensburg**
- Doctor's Practice **Gelsenkirchen**
- Doctor's Practice **Gladbeck**
- Doctor's Practice **Göppingen**
- Doctor's Practice **Gotha**
- Doctor's Practice **Gröbenzell**
- Doctor's Practice **Groitzsch**
- Doctor's Practice **Gummersbach**
- Doctor's Practice **Halle Saale**
- Doctor's Practice **Hamm**
- Doctor's Practice **Hannover**
- Doctor's Practice **Heinsberg**
- Doctor's Practice **Herne**
- Doctor's Practice **Herten**
- Doctor's Practice **Heusweiler**
- Doctor's Practice **Hildesheim**
- Doctor's Practice **Holzminden**
- Doctor's Practice **Homburg**
- Doctor's Practice **Iserlohn**
- Doctor's Practice **Kall**
- Doctor's Practice **Kaltenkirchen**
- Doctor's Practice **Krefeld**

- Doctor's Practice **Langenfeld**
- Doctor's Practice **Lemgo**
- Doctor's Practice **Leutkirch**
- Doctor's Practice **Leverkusen**
- Doctor's Practice **Lichtenstein**
- Doctor's Practice **Lippstadt**
- Doctor's Practice **Ludwigsburg**
- Doctor's Practice **Lutherstadt Eisleben**
- Doctor's Practice **Mannheim**
- Doctor's Practice **Mechernich**
- Doctor's Practice **Miltenberg**
- Doctor's Practice **Mönchengladbach**
- Doctor's Practice **Mühlacker**
- Doctor's Practice **Niederkassel**
- Doctor's Practice **Nienburg**
- Doctor's Practice **Nordhausen**
- Doctor's Practice **Nordhorn**
- Doctor's Practice **Nürnberg**
- Doctor's Practice **Osnabrück**
- Doctor's Practice **Papenburg**
- Doctor's Practice **Potsdam**
- Doctor's Practice **Prien**
- Doctor's Practice **Rastatt**
- Doctor's Practice **Regensburg**
- Doctor's Practice **Rendsburg**
- Doctor's Practice **Saarbrücken**
- Doctor's Practice **Schwabach**
- Doctor's Practice **Seesen**
- Doctor's Practice **Stockach**
- Doctor's Practice **Stralsund**
- Doctor's Practice **Stuttgart**
- Doctor's Practice **Tettnang**

- Doctor's Practice **Tirschenreuth**
- Doctor's Practice **Trier**
- Doctor's Practice **Troisdorf**
- Doctor's Practice **Velbert**
- Doctor's Practice **Völklingen**
- Doctor's Practice **Warstein**
- Doctor's Practice **Wedel**
- Doctor's Practice **Wesel**
- Doctor's Practice **Witten**
- Doctor's Practice **Zwickau**
- Doctor's Practice **Baesweiler**
- Doctor's Practice **Bautzen**
- Doctor's Practice **Bogen**
- Doctor's Practice **Brake**
- Doctor's Practice **Bremen**
- Doctor's Practice **Delmenhorst**
- Doctor's Practice **Ergolding**
- Doctor's Practice **Hemer**
- Doctor's Practice **Kerpen-Sindorf**
- Doctor's Practice **Rüsselsheim**
- Doctor's Practice **Sömmerda**
- Doctor's Practice **Wilhelmshaven**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/11/03**
- Target Sample Size: **1250**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

at least 65 years of age; symptoms of overactive bladder; prescription of Spasmex 45mg coated tablets

Exclusion criteria

younger than 65 years of age

Addresses

- **Primary Sponsor**

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  Germany

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/10/30**

Trial Publications, Results and other documents

- Paper **Ivchenko et al. 2018 Anticholinergic burden and comorbidities**

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.