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Persistence rate with medical treatment in patients with idiopathic or neurogenic overactive bladder

Submission date
03/03/2017

Recruitment status
No longer recruiting

Registration date
17/03/2017

Overall study status
Completed

Last Edited
18/04/2017

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
An overactive bladder is where a person regularly gets a sudden and compelling need or desire to pass urine. Many people suffer from overactive bladder. Most of these patients are treated first with anticholinergic drugs. Many of these patients are not taking these drugs after one year. The aim of this study is to find out whether patients continue to use the anticholinergic solifenacin after one year and the reason when they stop.

Who can participate?
Patients aged over 18 with overactive bladder who have been prescribed solifenacin

What does the study involve?
Participants receive the same medication as they normally would, and are contacted by telephone at 1, 3, 6 and 12 months after starting solifenacin. They are asked whether they are still taking the medication, about possible side effects, and if they have stopped taking the medication, what are their reasons for stopping.

What are the possible benefits and risk of participating?
Participants receive feedback about their use of solifenacin, and the information could be used to improve the future use of the medication. There are no risks involved.

Where is the study run from?
Erasmus Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
June 2009 to July 2013

Who is funding the study?
Erasmus Medical Center (Netherlands)

Who is the main contact?
Dr Bertil Blok

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MEC-2009-094

Study information

Scientific Title
Real life persistence rate with antimuscarinic treatment in patients with idiopathic or neurogenic overactive bladder: a prospective cohort study with solifenacin

Study objectives
To investigate the persistence rate in real life among patients with idiopathic or neurogenic overactive bladder (OAB) who were prescribed solifenacin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Erasmus Medical Center Ethics Committee, 09/04/2009, ref: MEC-2009-094

Study design

Prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format. A paper version of the patient information sheet is available in Dutch upon request. Please use the contact details below

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

Interventions
After giving informed consent, patients older than 18 years and newly prescribed solifenacin because of complaints of idiopathic or neurogenic OAB, were included. Patients who had used anticholinergic drugs less than 7 days before they started solifenacin were excluded. The starting dose was chosen by the doctor who prescribed the solifenacin but could be adjusted during the study period. Participants were allowed to continue possible other urologic medications, for example alfa-blockers, but not other anticholinergic drugs. Telephone surveys were taken at 1, 3, 6 and 12 months after starting solifenacin. The patients were asked whether they were continuing the medication. They were also interviewed about possible side effects and if they had discontinued the therapy, what had been reasons for stopping.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Persistence of usage, measured by telephone surveys at 1, 3, 6 and 12 months

Secondary outcome measures
Reasons for stopping medication, measured by telephone surveys at 1, 3, 6 and 12 months

Overall study start date
01/06/2009

Completion date
01/07/2013

Eligibility

Key inclusion criteria
1. Patients older than 18 years
2. Idiopathic or neurogenic overactive bladder
3. Newly prescribed solifenacin

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
123

Key exclusion criteria
1. Patients not on solifenacin
2. Patients who had used anticholinergic drugs less than 7 days before they started solifenacin

Date of first enrolment
01/06/2009

Date of final enrolment
01/07/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3015 CE

Sponsor information

Organisation
Erasmus Medical Center

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medisch Centrum

Alternative Name(s)
Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
The study has been submitted for publication

Intention to publish date
01/07/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Marloes Tijnagel (mtijn@hotmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		16/03/2017	20/03/2017	No	No
Results article	results	13/04/2017		Yes	No