

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

Submission date 03/03/2017	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 17/03/2017	Overall study status Completed	☐ Protocol
Last Edited 18/04/2017	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☒ 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

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?
Results article	results	13/04/2017		Yes	No
Basic results		16/03/2017	20/03/2017	No	No