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The efficacy of mirabegron additional therapy for elderly male lower urinary tract symptoms after treatment with α1-adrenergic receptor blocker

Submission date
04/07/2016

Recruitment status
No longer recruiting

Registration date
08/07/2016

Overall study status
Completed

Last Edited
30/11/2020

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
Overactive bladder syndrome (OAB) is a common condition with symptoms such as an urgent feeling to go to the toilet, going to the toilet often and sometimes leaking urine before getting to a toilet. Bladder training often cures the problem and sometimes medication is given at the same time. Mirabegron is a β3-adrenoreceptor agonist developed for treatment of overactive bladder. α1-Adrenergic receptor blockers work well for lower urinary tract symptoms (LUTS) in male patients. However, it is not known how well mirabegronl treatment in elderly male patients with persistent male LUTS performs, especially in OAB after monotherapy (therapy with a single drug) with α1-adrenergic blockers. The aim of this study is to clarify the efficacy of mirabegron as an additional treatment for male elderly patients with LUTS.

Who can participate?
Men aged at least 65 with LUTS

What does the study involve?
Participants have their usual treatment for LUTS but are also given 50g of mirabegron daily for 12 weeks. Treatment is assessed by seeing whether OAB symptoms improve.

What are the possible benefits and risks of participating?
It is expected that participants will benefit from improvement of their overactive bladder symptoms. The risk of participating is minimal, but some people may find it painful to urinate (side effect of mirabegron)

Where is the study run from?
Department of Urology and Renal Transplantation, Nagasaki University Hospital (Japan)

When is the study starting and how long is it expected to run for?
January 2012 to March 2015

Who is funding the study?
Nagasaki University Hospital (Japan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The efficacy of mirabegron additional therapy for lower urinary tract symptoms after treatment with α1-adrenergic receptor blocker monotherapy: prospective analysis of elderly men

Study objectives
The efficacy of mirabegron additional treatment in elderly male patients with persistent male lower urinary tract symptoms (LUTS), especially overactive bladder (OAB) symptoms after monotherapy with α1-adrenergic blockers, is not fully understood. Hence, the aim of study is to clarify it.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Nagasaki University Hospital Ethical Committee, 17/11/2011, ref: 11120267

Study design
Interventional non-randomized single site study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Persistent male lower urinary tract symptoms (LUTS) and overactive bladder (OAB) symptoms

Interventions
The patients continued all of their prescribed drugs during this study period. Before and 12 weeks after mirabegron (Betanis®, Astellas Pharma Inc., Tokyo, Japan; 50 mg once daily) treatment was added to a previous α1-adrenergic receptor blocker for urinary symptoms, efficacy of the treatment was evaluated using the OABSS and International Prostate Symptom Score (IPSS) to assess subjective symptoms, and uroflowmetry and PVR was used to assess objective symptoms. We measured the maximum flow rate (Qmax) on free uroflowmetry and PVR using transabdominal ultrasound sonography. Moreover, before mirabegron add-on treatment was administered, the prostate volume (PV) was evaluated using transabdominal ultrasound sonography. During the clinical study, the current α1-adrenergic receptor blocker that the patients had been taking orally was not changed to a different one.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
1. The change of total overactive bladder symptom score
2. The change of total international prostate symptom score

3. Voided volume
4. Maximum flow rate
5. Post void residual urine volume

Measured at between baseline and 12-weeks after treatment

Secondary outcome measures
1. The subscore of overactive bladder score
2. The subscore of intrenational prostate symptom score

Measured at between baseline and 12-weeks after treatment

Overall study start date
05/01/2012

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Male patients who had persistent lower urinary tract symptom and particularly overactive bladder symptoms, and had been taking a regular dose of α1-adrenergic receptor blockers for more than 12 weeks.
2. 65 years or older
3. total overactive bladder symptom score of 3 or more points with urinary urgency at least once per week

Participant type(s)
Patient

Age group
Senior

Sex
Male

Target number of participants
50 patients

Total final enrolment
50

Key exclusion criteria
1. Post void urine volume of 50 mL
2. History of urinary retention
3. Prior diagnosis of neurogenic bladder
4. Urethral stricture
5. Severe hypertension (systolic blood pressure ≥ 180 mmHg and/or diastolic blood pressure ≥ 110 mmHg) not well controlled by medication

6. Renal insufficiency (glomerular filtration rate < 30 mL/min/1.73 m2)
7. Liver impairment
8. Intention to have a child
9. Urological malignancy
10. Patients taking any anti-muscarinic drugs

Date of first enrolment
21/01/2012

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
Japan

Study participating centre
Department of Urology and Renal Transplantation, Nagasaki University Hospital
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/058h74p94

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Nagasaki University Hospital

Results and Publications

Publication and dissemination plan
Planning to publish the results in September 2016.

Intention to publish date
30/09/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/07/2016	30/11/2020	Yes	No