ISRCTN19242032 https://doi.org/10.1186/ISRCTN19242032

STOP: Satisfaction and Tolerability in Overactive bladder Patients (less than 65 years versus greater than or equal to 65 years)

Submission date	Recruitment status	[_] Prospectively registered
12/06/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/07/2012	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
018-010

Study information

Scientific Title

Acronym

STOP

Study objectives
Patients and physician satisfaction with study drug 018 will not be different in elderly and non-elderly patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval for the lead centre was obtained from IRB Services, Aurora, Ontario (Canada) on November 23, 2006. All other participating centres obtained ethics approval before recruiting study patients.

Study design
Multi-centred open label trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Oral anticholinergic-antispasmodic (018) over a four-week open label phase.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Study drug 018

Primary outcome(s)
Measured after four weeks of treatment:
1. Quality of life
2. Patient and physician satisfaction

Key secondary outcome(s))
Measured after four weeks of treatment:
1. Tolerability
2. Cognitive status
3. Adverse events

Completion date

31/12/2007

Eligibility

Key inclusion criteria
1. Males or non-pregnant, non-nursing females greater than or equal to 18 years of age
2. Diagnosis of overactive bladder and currently experiencing incontinent episodes and frequent micturitions or urgency
3. Newly diagnosed patients or patients not currently taking medication for overactive bladder
4. Capable of completing questionnaires in English or French

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patient who will initiate treatment with any drug prescribed for the treatment of overactive bladder (except oestrogen) during the study period
2. Patient with a primary diagnosis of stress incontinence or a concurrent diagnosis of functional or overflow incontinence
3. Patients with conditions contra-indicating anticholinergic therapy or have hepatic or renal disease
4. Patients using an indwelling catheter or who had bladder electrostimulation therapy or participated in bladder training within the previous 14 days prior to study entry

Date of first enrolment
07/01/2007

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Canada

Study participating centre

Purdue Pharma
Pickering
Canada
L1W 3W8

Sponsor information

Organisation
Purdue Pharma Canada

ROR
https://ror.org/023sxys58

Funder(s)

Funder type
Industry

Funder Name
Purdue Pharma Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes