An Open-Label, Multi-Center, Follow-Up Study Designed to Evaluate the Long-Term Effects of Rasagiline in Parkinson's Disease Subjects who Participated in the ADAGIO Study

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- To investigate whether the effect of early-start rasagiline treatment (according to the ADAGIO study protocol) provided long term benefits over delayed-start.- To investigate the long-term effects of rasagiline in PD subjects who participated in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON36779

Source
ToetsingOnline

Brief title
ADAGIO Follow-Up

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: TEVA Pharma
Source(s) of monetary or material Support: Teva Pharma

Intervention

Keyword: Adagio, long-term effects, Parkinson, rasagiline

Outcome measures

Primary outcome

As this is a single arm study, all statistical analysis will be descriptive in

nature.

Secondary outcome

NA

Study description

Background summary

Parkinson*s disease is a progressive neurological disease, characterized by tremor, muscle rigidness, slowness in movement and loss of balance. Most of the available medications for Parkinson*s disease are symptomatic therapies. These therapies provide effective control of symptoms, particularly in the early phases of the disease.
Rasagiline is a potent, selective irreversible inhibitor of the enzyme monoamine oxidase B (MAO-B). The inhibition of this enzyme, that metabolizes dopamine in the human brain, raises the levels of dopamine. Preclinical studies using multiple experimental models have also shown that, independent of its MAO-B inhibitory activities, rasagiline is able to protect neurons against injuries and stress.

The results of the ADAGIO study suggested that Azilect 1 mg may have a beneficial effect on the clinical progression of Parkinson*s disease. This study will follow up on the long term clinical condition of subjects who participated in the ADAGIO study.

Study objective

- To investigate whether the effect of early-start rasagiline treatment (according to the ADAGIO study protocol) provided long term benefits over delayed-start.
- To investigate the long-term effects of rasagiline in PD subjects who participated in the ADAGIO study and have continued on rasagiline treatment.

Study design

This is an open-label, multi-center, follow-up study.
Eligible subjects, who participated in the ADAGIO trial, and who sign an approved informed consent form, will be enrolled into the study by their original centers and will continue to receive 1 mg rasagiline once a day. Tablets will be supplied by the Sponsor and given according to the local label. Study drug will be dispensed every 3, 6 or 12 months (as permitted and decided at each site).
Use of any other anti-PD treatments is permitted as deemed necessary by the treating physician (according to the subject's clinical status). Subjects will be followed for AE and various aspects of disease progression every three months, for up to two years in two visit types: short and long visits. Short visits will be conducted either over the phone or as on-site visits at the discretion of the investigator. Long visits will be conducted annually on-site.

Subjects who stop rasagiline treatment during the study will continue to be followed as per the protocol (according to their willingness). The data collected will be assessed every six months, and based on this analysis it will be decided if to continue with the follow-up study.

Intervention

All participants in the study will receive the same dose of rasagiline, and will take one tablet per day. In addition the subjects will be able to receive other treatments for Parkinson*s disease as deemed appropriate by their study physician.

Study burden and risks

The following side effects have been reported in placebo controlled clinical trials:
Very common (more than 10% of the patients): Abnormal movements (dyskinesia), headache
Common (between 1-10% of the patients): Abdominal pain, accidental injury (primary falls), allergic reaction, fever, flu syndrome, malaise, neck pain, chest pain (angina pectoris), low blood pressure when rising to a standing position (postural hypotension), anorexia, constipation, dyspepsia, dry mouth, vomiting, abnormal results of blood tests (leucopenia), joint pain

(arthralgia), arthritis, inflammation of tendon (tenosynovitis), weight loss, abnormal dreams, difficulty in muscular co-ordination (ataxia), depression, vertigo, prolonged muscle contractions (dystonia), rhinitis, contact dermatitis, rash, blistering rash (vesiculobullous rash), blood-shot eyes (conjunctivitis), urinary urgency
Uncommon (between 0.1-1% of the patients): Stroke (cerebrovascular accident), heart attack (myocardial infarct)
In addition, skin cancer was reported in around 1% of patients in the placebo controlled clinical trials. Nevertheless, scientific evidence suggests that Parkinson*s disease, and not any drug in particular, is associated with a higher risk of skin cancer (not exclusively melanoma).
Parkinson's disease is associated with symptoms of hallucinations and confusion. In post marketing experience these symptoms have also been observed in Parkinson's disease patients treated with rasagiline. Rasagiline can increase the effect of certain drugs including over the counter cough and cold remedies, leading to serious elevations of blood pressure. Rasagiline may have the potential to interact with some anti-depressants. This drug interaction may lead to mild symptoms such as upset stomach, sleep difficulty, restlessness, or agitation. In rare cases the symptoms may be severe and include loss of balance, muscle spasms, seizures (convulsions), possible kidney damage, and even death.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients who participated in the Adagio study
2. Patients who are currently using rasagiline, are willing to restart treatment, and in the opinion of the investigator will gain clinical benefit from restarting treatment)
3. Patients with Parkinson's disease

Exclusion criteria

1. Subjects who have discontinued rasagiline treatment due to an adverse event and have not restarted rasagiline treatment subsequently.
2. Subjects who cannot be given rasagiline due to any exclusion based on the local label (including pregnancy or nursing women) or due to the use of medications contraindicated for concomitant use with rasagiline according to local label
3. Subjects with a medical condition that is considered by the investigator as significant enough to prevent participation

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-01-2010

Enrollment:	7
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Azilect
Generic name:	rasagiline
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-06-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-12-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-05-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-05-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	23-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	clinicaltrials.gov (nummer nog niet bekend)
EudraCT	EUCTR2009-011541-24-NL
CCMO	NL28362.003.09