Project REAL FIB: atrial fibrillation in real Praxis register

Submission date	Recruitment status	Prospectively registered
09/03/2010	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
06/04/2010	Completed	Results
Last Edited	Condition category	Individual participant data
06/04/2010	Circulatory System	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Robert Hatala

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2009, protocol version 6.0, 18.01.2010

Study information

Scientific Title

Project REAL FIB - atrial fibrillation in real Praxis register: a multicentre, non-interventional, observational and prospective study

Acronym

REAL FIB

Study objectives

Charting of therapeutic methods indicated by medical doctors of different specialisations (cardiologists, internists) in prevention of atrial fibrillation from all over the country.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Multicentric Ethics Committee approved on the 21st December 2009 (ref: 108728/2009-11)

Study design

Multicentre non-interventional observational prospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Diagnostic

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

Atrial fibrillation (AF)

Interventions

This is a non-interventional study, all interventions will be performed according to common clinical Praxis in the management and follow up of patients with atrial fibrillation on treatment.

Baseline visit:

- 1. Demographic data collection
- 2. Risk factors assessment: height, weight, age, patient history (hypertension, age when AF diagnosed, coronary disease, heart failure, New York Heart Association [NYHA] classification, systolic dysfunction, ejection fraction, diastolic dysfunction, sick sinus syndrome, cardiostimulator, implantable cardioverter-defibrillator [ICD], history of cardiovascular surgery, other heart diseases, mitral valve disease and type, diabetes mellitus), blood sugar level, dyslipidaemia, cholesterol level, low density lipoprotein [LDL]-cholesterol level, chronic renal

insufficiency, creatinine, urea, ions, thyreopathy, body mass index [BMI], transient ischaemic attack [TIA]/cerebrovascular accident [CVA], alcohol abuse, family history for AF, CHADS score 3. AF characteristics

4. Treatment strategy (rhythm control, frequency control, thrombembolism prevention, other treatment)

Follow up (6 months):

- 1. Basic data
- 2. Accidental events
- 3. Treatment strategy

Follow up (12 months):

- 1. Basic data
- 2. Accidental events
- 3. Treatment strategy

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. To assess clinical profile of patients with atrial fibrillation
- 2. To assess contemporary treatment modalities and its effectiveness
- 3. To observe occurence of cardiovascular events prospectively

Secondary outcome measures

1. To analyse correlation between treatment modalities indicated by medical doctors of different specialisations (cardiologists, internists) in prevention of atrial fibrillation 2. To collect treatment safety data

Overall study start date

01/02/2010

Completion date

30/04/2011

Eligibility

Key inclusion criteria

All patients diagnosed with atrial fibrillation (any age, either sex)

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

1000

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/02/2010

Date of final enrolment

30/04/2011

Locations

Countries of recruitment

Slovakia

Study participating centre Národný ústav srdcových a cievnych chorôb

Bratislava 37 Slovakia 833 48

Sponsor information

Organisation

Masaryk University (Czech Republic)

Sponsor details

c/o Doc. RNDr. Ladislav Duek, Ph.D.
Institute of Biostatistics and Analyses
Faculty of Medicine and the Faculty of Science
Kamenice 2
Brno-Bohunice
Czech Republic
625 00
dusek@iba.muni.cz

Sponsor type

University/education

Website

http://www.muni.cz/

ROR

https://ror.org/02j46qs45

Funder(s)

Funder type

University/education

Funder Name

Masaryk University (Czech Republic) - Institute of Biostatistics and Analyses at the Faculty of Medicine and the Faculty of Science

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration