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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

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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
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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