

Project REAL FIB: atrial fibrillation in real Praxis register

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

Completion date

30/04/2011

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration