ISRCTN04561582 https://doi.org/10.1186/ISRCTN04561582

Trial on the effect of biventricUlar pacinG in patients with bradycardia prEserved LV functioN, with the aim of Decreasing Heart failure and ATrial fibrillation.

Submission date 27/05/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 16/08/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/08/2011	**Condition category** Circulatory System	[_] Individual participant data [_] 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

Protocol serial number
NR9190-3/2007

Study information

Scientific Title

TUGENDHAT Study

Acronym
TUGENDHAT

Study objectives
Aim of this study is to compare standard AV sequential pacing versus biventricular pacing in the patients with conventional indication for permanent heart pacing (primary bradycardia indication) accompanied by documented left ventricular dysfunction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Homolce Hospital Ethics Committee, 12 June 2008, ref: IBA-KS-2008-01 - Tugendhat

Study design
The multicentre, observational, prospective study with 5 years follow-up visits

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
AV block, Sick Sinus Syndrome - Bradycardia form

Interventions
1. The study contains 120 patients randomized into right ventricular and biventricular pacing group with cross-over switch of pacing modes after six months
2. Standard descriptive statistics will be used for the analysis, continuous paremeters as age, weight, body mass index were described by median and fifth and ninety-fifth percentile, occurence of categorical parameters was described by their count and percentages.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Electrocardiographic parameters (ECG)
2. Echocardiographic parameters (LV Ejection Fraction)
3. Evaluation of NYHA class
4. Evaluation of Quality of Live (Minnesota Living with Heart Failure questionnaire)

Key secondary outcome(s))
Atrial Fibrillation burden hospitalization for Heart Failure complication of pacing

Completion date

01/12/2015

Eligibility

Key inclusion criteria
1. Bradycardia pacing indication
2. Subject has stable medication (nitrates, diuretics, betablockers) within the last 3 months 3. Echocardiographic exclusion of ventricular (inter-and intra) dyssynchrony
4. Willing and able to comply with the Clinical investigation Plan
5. Signed Informed consent form
6. Aavailability for follow-up visits

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Age less 18 years
2. Indication for biventricular pacing
3. LV EF less than15%
4. Stable NYHA IV
5. Intravenous diuretics, ionotropics medication
6. Enrollment in a concurrent study that may confound the results of this study
7. Post heart transplant or awaiting heart transplantation
8. Renal insufficiency requiring dialiysis
9. Anticipation of poor compliance
10. Pregnancy
11. Life expectancy less than 12 months
12. The inform consent form not signed

Date of first enrolment
01/07/2008

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
Czech Republic

Study participating centre
Olomouc University Hospital
Olomouc
Czech Republic
775 20

Sponsor information

Organisation
Olomouc University Hospital (Czech Rebublic)

ROR
https://ror.org/01jxtne23

Funder(s)

Funder type
Research organisation

Funder Name
IGA (Czech Republic), ref: NR9190-3/2007

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration