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A study of implantable cardiac defibrillators (ICD; a device used to correct irregular heart rhythm) in a Chinese population

Submission date 21/05/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/06/2021	**Overall study status** Completed	
Last Edited 22/07/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
An implantable cardioverter-defibrillator (ICD) is a small battery-powered device placed in your chest to monitor your heart rhythm and detect irregular heartbeats. An ICD can deliver electric shocks via one or more wires connected to your heart to fix an abnormal heart rhythm.
The subcutaneous implantable cardioverter–defibrillator (S-ICD) was designed to avoid complications related to the transvenous implantable cardioverter–defibrillator (TV-ICD) lead by using an entirely extrathoracic placement. The safety and effectiveness of S-ICD have been exhibited by many international multicenter studies, however, none of these observational studies involved the Chinese population.
This study aims to observe the incidence of inappropriate shock (IAS) at 18 months after S-ICD implantation in the Chinese population.

Who can participate?
Patients aged 18 years or older who are recommended to have ICD therapy

What does the study involve?
All the subjects will be followed up for 18 months after the procedure. The intraoperative parameters and complications, the occurrence of inappropriate shock, appropriate shock, ATP therapy, successful conversion, cardiac death, and device-related complication will be analyzed.

What are the possible benefits and risks of participating?
The treatment and follow-up frequency included in this observational study consists of the real-world clinic process and conforms to the consensus recommendation. Thus this is no additional benefits or risks.

Where is the study run from?
The First Affiliated Hospital of Xinjiang Medical University (China)

When is the study starting and how long is it expected to run for?
January 2021 to April 2024

Who is funding the study?
Boston Scientific Inc (USA)

Who is the main contact?
Tang Baopeng, tangbaopeng111@163.com

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The application prospect of subcutaneous and transvenous ICD in Chinese population with primary prevention indication

Acronym
SCOPE

Study objectives
Proportion of subjects that free from inappropriate shock through month 18 after the procedure is more than the performance goal of 90.3%.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 03/06/2021, The First Affiliated Hospital of Xinjiang Medical University (No 137, Liyu South Road, Urumqi, Xinjiang, China, 830054; +86 15276535185; 393518493@qq.com), ref: K202103-06

Study design
Multicenter prospective observational cohort

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Chinese population with primary prevention indication for ICD therapy

Interventions
All the subjects will be followed up for 18 months after the procedure to observe the occurrences of inappropriate shock, appropriate shock, device related complications and cardiac death.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
implantable cardiac defibrillator

Primary outcome(s)
Occurrence of inappropriate shock will be determined according the programming reports at 1, 3, 6, 12, 18 months after the procedure.

Key secondary outcome(s))
1. Occurrence of appropriate shock will be determined according the programming reports at 1, 3, 6, 12, 18 months after the procedure
2. Success rate of conversion will be determined according the programming reports at 1, 3, 6, 12, 18 months after the procedure
3. Occurrence of cardiac death and device related complications will be determined by clinicians at 1, 3, 6, 12, 18 months after the procedure

Completion date
01/04/2024

Eligibility

Key inclusion criteria
1. Age >18 years
2. The subjects met the class I or class II indications for ICD therapy for primary prevention
3. Subjects can be screened by S-ICD ECG
4. The subjects are willing and able to sign informed consent and attend all relevant visits on time

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnant
2. Subjects are participating in other clinical trials, which may affect this study
3. The researchers determined that the subjects were not suitable for S-ICD implantation, such as patients need or will need pacing therapy for bradycardia; Subjects with known ventricular tachycardia at a rate below 170 beats per minute or with refractory recurrent monomorphic ventricular tachycardia that could not be managed with medication or ablation therapy
4. Subjects implanted with a transvenous CRT-D or with history of pacemaker or ICD
5. Subjects with paced rhythms at baseline or post-implant of TV-ICD
6. Life expectancy <18 months

Date of first enrolment
21/06/2021

Date of final enrolment
01/10/2023

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of Xinjiang Medical University
No 137
Liyu South Road
Urumqi

China
830054

Study participating centre
Zhongshan Hospital
No. 1609 Xietu Road
Xuhui District
Shanghai
China
200032

Study participating centre
Fuwai Hospital
No.167 Beilishi Road
Xicheng District
Beijing
China
100037

Study participating centre
Anzhen Hospital
No. 2 Anzhen Road
Chaoyang District
Beijing
China
100029

Study participating centre
Anhui Provincial Hospital
No. 1 Swan Lake Road
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Hefei
China
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Study participating centre
Zhejiang Green City Hospital
No. 409 Gudun Road
Xihu District

Hangzhou
China
310012

Study participating centre
Tianjin Chest Hospital
No. 261 Taierzhuang South Road
Jinnan District
Tianjin
China
300222

Study participating centre
Sun Yat-sen Memorial Hospital
No. 107 Yanjiang West Road
Yuexiu District
Guangzhou
China
510030

Study participating centre
Meizhou Hospital Affiliated to Sun Yat-sen University
No.34 Huangtang
Meijiang District
Meizhou
China
514031

Study participating centre
The First Affiliated Hospital of Zhengzhou University
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27th District
Zhengzhou
China
450000

Study participating centre
Yunnan Fuwai Cardiovascular Disease Hospital
Intersection of Shahe North Road and Jinzhou Road
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Wuhua District

Kunming
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650000

Study participating centre
The Second Affiliated Hospital of Army Military Medical University
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Chongqing
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400037

Study participating centre
The Third Xiangya Hospital of Central South University
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Changsha
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410200

Study participating centre
Sichuan Provincial People's Hospital
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Chengdu
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610072

Study participating centre
Shanghai Chest Hospital
No. 241 Huaihai West Road
Xuhui District
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200030

Study participating centre
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The First Affiliated Hospital of Xi 'an Jiaotong University
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Study participating centre
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Study participating centre
The Second Affiliated Hospital of Harbin Medical University
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Sponsor information

Organisation
Boston Scientific (United States)

ROR
https://ror.org/0385es521

Funder(s)

Funder type
Industry

Funder Name
Boston Scientific Corporation

Alternative Name(s)
Boston Scientific, Boston Scientific Corp., BSC

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	24/02/2024	22/07/2025	Yes	No
Protocol file		08/07/2021	No	No