

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

<b>Submission date</b> 21/05/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/06/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/07/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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

**Contact name**  
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## Additional identifiers

## 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  
Government District  
Hefei  
China  
230031

**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**

No. 1 Jianshe East Road  
27th District  
Zhengzhou  
China  
450000

**Study participating centre****Yunnan Fuwai Cardiovascular Disease Hospital**

Intersection of Shahe North Road and Jinzhou Road  
Pan-Asia Science and Technology New District  
Wuhua District  
Kunming  
China  
650000

**Study participating centre**

**The Second Affiliated Hospital of Army Military Medical University**

No. 183 Xinqiaozheng Road  
Shapingba District  
Chongqing  
China  
400037

**Study participating centre**

**The Third Xiangya Hospital of Central South University**

No. 138 Tongzipo Road  
Yuelu District, Hexi  
Changsha  
China  
410200

**Study participating centre**

**Sichuan Provincial People's Hospital**

No. 32 West Second Section  
First Ring Road  
Qingyang District  
Chengdu  
China  
610072

**Study participating centre**

**Shanghai Chest Hospital**

No. 241 Huaihai West Road  
Xuhui District  
Shanghai  
China  
200030

**Study participating centre**

**Shanxi Provincial Cardiovascular Hospital**

No. 18 Tianfen Street  
Taiyuan City  
Taiyuan  
China  
030024

**Study participating centre**

**The First Affiliated Hospital of Kunming Medical College**  
No. 295 Xichang Road  
Wuhua District  
Kunming  
China  
650032

**Study participating centre**  
**The First Affiliated Hospital of Xi 'an Jiaotong University**  
No. 277 Yanta West Road  
Yanta District  
Xi 'an  
China  
710061

**Study participating centre**  
**West China Hospital of Sichuan University**  
No.37 Guoxue Lane  
Wuhou District  
Chengdu  
China  
610041

**Study participating centre**  
**Henan Provincial People's Hospital**  
No.7 Weiwu Road  
Jinshui District  
Zhengzhou  
China  
450000

**Study participating centre**  
**The Second Affiliated Hospital of Harbin Medical University**  
No. 246, Xuefu Road  
Nangang District  
Harbin  
China  
150001

**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?
<a href="#">Results article</a>		24/02/2024	22/07/2025	Yes	No
<a href="#">Protocol file</a>			08/07/2021	No	No