Case Report Form

Effects of intravenous and inhalation anesthesia on blood glucose and complications in patients with type 2 diabetes mellitus

Subject Initials	|____||____||____||____|
Study Center No.	|____||____||____||____|
Filter No.	|____||____||____||____|
Random No.	|____||____||____||____|
Study start date	d d m m m y y y y
Study end date	d d m m m y y y y

Investigator's Signature:_____

Form Maker：Department of Anesthesiology, West China Hospital, Sichuan University

Randomisation No.: |__||__||__||__| Subject initials: |__||__||__||__|

Screening Date: _____

DD MMM YYYY

Inclusion criteria:

Note: subjects whose one of the following is "No" cannot be included.	No	Yes
1. A confirmed diagnosis of type 2 diabetes mellitus;	☐	☐
2. Male or female 18 to 90 years of age;	☐	☐
3. American Society of Anesthesiologists class I, II, or III;	☐	☐
4. General surgery, operation time more than 2 hours;	☐	☐
5. Correctly understanding Chinese and express their wishes;	☐	☐
6. Provision of written informed consent.		

*If any inclusion criteria are ticked no then the patient is not eligible for the study.

Exclusion criteria:

Note: subjects whose one of the following is "Yes" cannot be included.	No	Yes
1.with a history of severe systemic diseases, metabolic disorders, diabetic ketoacidosis or hyperglycemia, diabetic neuropathy, diabetic nephropathy, hepatorenal dysfunction, and neuromuscular disease;	☐	☐
2. with pancreatic cancer, islet cell tumor;	☐	☐
3.being not suitable for the patients according to the doctors or surgeons;	☐	☐
4. Inability to complete research questionnaires;		
5. rejection of randomization.		

* If any exclusion criteria are ticked yes then the patient is not eligible for the study.

Fill in the screening number: |__||__||__||__|

* Please fill in the screening number on the cover page and each page after that for the sequence number of subjects entering the screening for the center, and continue to fill in.

Demographic data:

Date of birth:|__||__||__||__||__||__||__||__| （Consistent with the front page of medical record）
Gender:☐ male ☐ female Nation: ☐ Chinese ☐ Other nationalities: ____
ID number：|__||__||__||__||__||__||__||__||__||__||__||__||__||__||__||__||__||__|

Investigator’s signature: _____ Date:_____

DD MMM YYYY

Basic information of subject:

<table>
<tr><td>Name：_____</td><td colspan="2">Nursing unit:|__||__| Bed No.:|__||__|
Inpatient No.:|__||__||__||__||__||__||__||__||__||__||__|</td></tr>
<tr><td>Age (yrs): |__||__|</td><td>Height (m): |__||__||__|
Weight (kg): |__||__||__|</td><td>BMI (kg/m^2): |__||__|. |__|
ASA: |__||__|</td></tr>
<tr><td colspan="3">Fasting blood glucose: |__||__| |__||__|mmol/L Postprandial blood glucose: |__||__| |__||__|mmol/L
Preoperative blood glucose control: ☐Diet control ☐Insulin control ☐Oral antidiabetic control
☐Insulin and oral antidiabetic control</td></tr>
<tr><td colspan="3">contact information: Subject's phone No.: |__||__||__||__||__||__||__||__||__||__||__|
Please confirm that the contact person is the one who can easily contact you (the subject) after discharge. This phone can contact you personally.
First contact person: _____ Phone No.: |__||__||__||__||__||__||__||__||__||__||__|</td></tr>
</table>

History collection:

Name of previous disease	Diagnosis time
	|__||__||__||__||__||__|
	|__||__||__||__||__||__|
	|__||__||__||__||__||__|
	|__||__||__||__||__||__|
Name of previous operation	Operation time
	|__||__||__||__||__||__|

Random grouping table of subjects

Whether the relevant departments were approved by the doctors to participate in the study?

☐ No ☐ Yes

Random grouping scheme: ☐Nondynamic random grouping ☐Dynamic random grouping

Investigator's signature: _____ Date:_____

DD MMM YYYY

Randomisation No.: |__||__||__||__| Subject initials: |__||__||__||__|

Whether the early information of subjects is completely collected, recorded and entered?

☐ No, the subject has not completed the evaluation and will not be given a random number.

☐ Yes, please open the random envelope according to the screening number or log in the random website to obtain the random number and the random grouping of the subject.

Randomisation No.: |__||__||__||__||__|

Group of subject: ☐ TIHA ☐ TIVA

Whether the random number has been filled in the cover?

☐ No ☐ Yes

* TIHA, Total inhalation anesthesia and TIVA, Total intravenous anesthesia.

Perioperative monitoring indicators

Anesthesia start time：_____ Anesthesia end time：_____

Operation start time: _____ Operation end time: _____

Operation time: _____ Anesthesia time: _____

1. Insulin (IU/mL**)**

30 minutes before operation: |__||__||__||__| 30 minutes after operation: |__||__||__||__|

2. Cortisol (ng/mL**)**

30 minutes before operation: |__||__||__||__| 30 minutes after operation: |__||__||__||__|

3. Blood glucose (mmol/L**)**

Preoperation:|__|__|__|	Operation start 2hr:|__|__|__|	Postoperation1hr: |__|__|__|
Immediate intubation: |__|__|__|	Operation start 3hr:|__|__|__|	Postoperation 2hr:|__|__|__|
skin incision:|__|__|__|	Skin suture:|__|__|__|	Postoperation1d:|__|__|__|
Operation start 1hr：|__|__|__|	Immediate extubation:|__|__|__|	Postoperation 2d:|__|__|__|

Investigator's signature: _____ Date:_____

DD MMM YYYY

4. **Insulin dosage (**IU**)**

During operation: |__||__||__||__|	1d after operation: |__||__||__||__|
Operation day: |__||__||__||__|	2d after operation： |__||__||__||__|

5**. Opioid dosage** (ug)

Remifentanil: |__||__||__||__| Sufentanil: |__||__||__||__|

6. **In and out volume (**ml**)**

Crystal input: |__||__||__||__| Crystal input: |__||__||__||__|

Blood transfusion:| __||__||__||__| Urine volume: |__||__||__||__|

7**.Perioperative vital signs**

	Preoperative	Intubation	skin incision	1hr after operation start	2hr after operation start	3hr after operation start	Skin suture	1hr after operation	2hr after operation
HR (Bpm)									
BP (mmHg)									
BIS								_	_
Spo_2 (%)									

*HR: Heart rate; BP: Blood pressure; BIS: bispectral index of EEG.

Postoperative complications record

Investigator's signature: _____ Date:_____

DD MMM YYYY

Randomisation No.: |__||__||__||__| Subject initials: |__||__||__||__|

Postoperative complications: ☐ No ☐ Yes→Please fill in the following form

	POD 1	POD 2	POD 3	Discharge	POD 30
Myocardial infarction	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes
Stroke	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes
Renal failure	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes
Anastomotic fistula	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes
Stress ulcer	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes
Incision Infection	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes
Pulmonary infection	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes
Other complications	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes
Death	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes	☐No ☐Yes

*POD, postoperative day.

Adverse Events

Has the participant experienced any Adverse Events since signing the Informed Consent? ☐No ☐Yes→Please fill in the following form

Adverse Events	Treatment	Outcomes (follow-up)

Investigator's signature: _____ Date:_____

DD MMM YYYY

Off study form

Date Off Study: __ __ / __ __ / __ __ __ __
(MM/DD/YYYY)

Date Last Study Medication Taken: __ __ / __ __ / __ __ __ __
(MM/DD/YYYY)

Reason Off Study (Please mark only the primary reason. Reasons **other than Completed Study** require explanation next to the response)

- ☐ Completed study
- ☐ Lost to follow-up _____
- ☐ Non-compliant participant _____
- ☐ Concomitant medication _____
- ☐ Medical contraindication _____
- ☐ Withdraw consent _____
- ☐ Death _____
- ☐ Other _____

Investigator's signature: _____ Date:_____
DD MMM YYYY