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Research on key technologies for perioperative risk management and control of age-related diseases

Submission date
20/04/2024

Recruitment status
No longer recruiting

Registration date
08/05/2024

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This project focuses on perioperative blood pressure management of elderly hypertensive patients and forms a management model of preoperative multidisciplinary evaluation and intervention. The project develops a mean arterial pressure (MAP)-guided blood pressure management program, explores the perioperative MAP management threshold of elderly hypertensive patients that can improve the prognosis of surgical patients, and studies the inflammatory mechanism of perioperative target organ injury in elderly hypertensive patients. To solve the bottleneck problem of perioperative clinical decision-making in elderly hypertension patients, the study will construct and promote key risk management technologies for elderly hypertension patients, and provide a basis and reference for the national development of the prevention and treatment system of elderly-related diseases and research on key technologies.

Who can participate?
Senior patients aged 65-80 years old who are planning to undergo general anesthesia and have a history of hypertension with systolic blood pressure ≥140mmHg and pulse pressure

What does the study involve?
In this study, the researchers will investigate how different approaches to managing blood pressure during surgery affect older individuals with hypertension. Elderly patients with hypertension who require surgery will be randomly assigned to one of three groups, each receiving a different method of blood pressure management during their operation. Brain activity and the function of the heart and kidneys will also be monitored throughout the surgical procedure. Following surgery, the researchers will conduct assessments on the day of the operation, as well as three days, one week, and one month post-surgery. These assessments will encompass factors such as blood pressure, pain levels, functional abilities, and any post-operative complications experienced. The objective is to determine the most effective blood pressure management strategy for elderly patients with hypertension, enabling healthcare

professionals to tailor treatment plans accordingly. Additionally, the study will examine the impact of reduced opioid pain medication usage during surgery on gastrointestinal function and recovery outcomes in elderly hypertensive patients undergoing colorectal tumor surgery.

What are the possible benefits and risks of participating?
The shift towards intraoperative management strategies and targeted blood pressure regulation for perioperative hypertension patients promises significant benefits. Implementing precise blood pressure targets during surgery can markedly reduce the incidence of postoperative complications, enhancing patient outcomes and recovery. Additionally, this approach allows for a more targeted prevention and treatment of hypertension, offering valuable insights for intervention decisions even among non-hypertensive populations. Through the construction and promotion of key risk management technologies, particularly for elderly hypertension patients, the healthcare system can better address the unique needs of this demographic, ultimately improving the overall prevention and treatment of elderly-related diseases.

However, the adoption of stringent blood pressure regulation during surgery carries inherent risks, particularly in elderly hypertension patients. Hypotension, a common consequence of aggressive blood pressure control, poses significant dangers such as increasing the risk of ischemic cardiovascular and cerebrovascular events like acute myocardial infarction and cerebral thrombosis. Moreover, hypotension can lead to renal failure, syncope, shock, and fractures, and in the long term, chronic hypotension may even contribute to depression and senile dementia. Thus, while targeting blood pressure during surgery offers benefits, it necessitates careful monitoring and management to mitigate the risks associated with hypotension, especially in vulnerable patient populations.

Where is the study run from?
People's Hospital of Xinjiang Uygur Autonomous Region, China

When is the study starting and how long is it expected to run for?
February 2021 to May 2023

Who is funding the study?
Government of Xinjiang Uygur Autonomous Region of China

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Research on key technologies for perioperative risk management in elderly patients

Study objectives
This project focuses on perioperative blood pressure management of elderly hypertensive patients, forms a management model of preoperative multidisciplinary evaluation and intervention, develops a mean arterial pressure (MAP)-guided blood pressure management program, explores the perioperative MAP management threshold of elderly hypertensive patients that can improve the prognosis of surgical patients, and studies the inflammatory mechanism of perioperative target organ injury in elderly hypertensive patients. To solve the bottleneck problem of perioperative clinical decision-making in elderly hypertension patients, construct and promote key risk management technologies for elderly hypertension patients, and provide a basis and reference for the national development of the prevention and treatment system of elderly-related diseases and research on key technologies.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/03/2021, Ethics Committee of People's Hospital of Xinjiang Uygur Autonomous Region (Xinjiang Uygur Autonomous Region People's Hospital, Xinjiang, Urumqi, 830001, China; +86 0991-8563857; quli1212@126.com), ref: KY2021031905

Primary study design
Interventional

Study design
Single-center interventional single-blind randomized controlled trial

Study type(s)
Prevention, Screening, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Perioperative blood pressure management in elderly patients with hypertension

Interventions
In this study, the influence of mean arterial pressure (MAP)-guided perioperative blood pressure management mode on the outcome of elderly hypertensive patients will be explored. This experiment calculated MAP as follows: MAP = diastolic pressure +1/3 pulse pressure difference. Invasive arterial blood pressure monitoring will be performed in all patients under anesthesia, and the sensors will be placed at the same level to observe the blood pressure changes in real time.

Elderly patients with hypertension who are planning to undergo general anesthesia will be randomly assigned to one of three groups, each implementing different levels of MAP management. The different levels will regulate MAP fluctuation ranges of 65-75 mmHg, 75-85 mmHg, and 85-95 mmHg during the operation, with multi-mode brain monitoring also in place.

The method of randomisation uses a random number table method:
Step 1: Generate random numbers: Use the "random number generator" of SPSS software to generate a random number with n x between 0 and 1, then define it as "random number" in "Transformation" - "Calculation variable" and set the numerical expression as "RV.UNIFORM (0,1)" to assign a random number to each patient for subsequent grouping.
Step 2: Randomized grouping: random numbers are grouped using the "visual subdivision" in "Transformation", the variation of subdivision is set as "group", divided into two groups, and the number of segmentation points is set as 1 to obtain the variable "group". Patients in group 1 are included in group A, and patients in group 2 are included in group B to complete random grouping.

Monitoring includes transcranial Doppler (TCD) for cerebral blood flow, regional oxygen saturation (rSO2) for cerebral metabolism, and bispectral index (BIS) for electroencephalogram (EEG), along with cardiac and renal function monitoring. Multidisciplinary assessments will be conducted on the day of surgery, as well as three days, one week, and one month after surgery. These assessments will cover various aspects such as blood pressure, pain score, functional status, cognitive function, speciality rehabilitation, surgical complications, the incidence of target organ injury (such as stroke, acute coronary syndrome, kidney injury), the average length of stay, ICU transfer rate, and postoperative outcomes. The aim is to determine the most suitable management threshold for perioperative MAP in elderly patients with hypertension, allowing for the formulation of individualized blood pressure management strategies for clinical diagnosis and treatment. Additionally, the study will examine the effects of low-opioid multimodal analgesia and anesthesia on intestinal function and prognosis in elderly hypertensive patients after colorectal tumor surgery.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Blood pressure level measured using the cuff three times a day, three days, one week and one month after surgery
2. Pain measured using a Visual Analog Scale (VAS) on the day, three days and one week after surgery
3. Body function and cognition measured using the unified standard rating scale after the operation
4. Rehabilitation will be measured by Specialists to establish a unified standard of physical examination to judge the rehabilitation of patients after the operation
5. Surgical complications, incidence of target organ injury (stroke, acute coronary syndrome, kidney injury), average length of stay, ICU transfer rate, and postoperative outcomes measured using data collected in patient medical records on the day, three days, one week, and one month after surgery

Key secondary outcome(s)
1. Perioperative stress indexes (blood glucose and cortisol) and inflammatory indexes (IL-6, TNF-α and C-reactive protein) measured using standard tests in venous blood samples before surgery, on the day after surgery, and on the second and third days after surgery, respectively, at

8 pm
2. Target organ function indicators (myocardial enzyme profile, urea nitrogen, creatinine, NSE and S100β) measured using standard tests in venous blood samples at 8 pm on the first day, three days and one week after surgery

Completion date
02/05/2023

Eligibility

Key inclusion criteria
1. Elderly patients, aged 65-80 years old
2. Patients with a history of hypertension with systolic blood pressure ≥140mmHg and pulse pressure difference ≥60mmHg
3. No contraindications to anesthesia
4. No signs of systemic infection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
1800

Key exclusion criteria
1. Tumors in other locations
2. A history of long-term use of sedative and analgesic drugs
3. Uncontrollable hypertension
4. Hyperglycemia
5. Severe liver and kidney dysfunction
6. Other contraindications for surgery

Date of first enrolment
01/01/2022

Date of final enrolment

01/03/2023

Locations

Countries of recruitment
China

Study participating centre
Xinjiang Anesthesia Management Medicine Clinical Research Center
People's Hospital of Xinjiang Uygur Autonomous Region, Xinjiang
Urumqi
China
830001

Sponsor information

Organisation
People's Hospital of Xinjiang Uygur Autonomous Region

ROR
https://ror.org/02r247g67

Funder(s)

Funder type
Government

Funder Name
Government of Xinjiang Uygur Autonomous Region of China

Alternative Name(s)
, People's Government of Xinjiang Uygur Autonomous Region, Xinjiang Uygur Autonomous Region Government, The Government of Xinjiang Uygur Autonomous Region of China

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/10/2024	10/06/2025	Yes	No