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Prospective feasibility and safety study of robotic-assisted radical prostatectomy with the new Toumai™ robotic system

Submission date
28/08/2025

Recruitment status
No longer recruiting

Registration date
01/09/2025

Overall study status
Completed

Last Edited
01/09/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Transitioning to a new robotic platform presents regulatory, logistical, and financial challenges. The Toumai™ (MicroPort® MedBot™) system has received European CE mark approval for urology, yet clinical experience outside China is limited. This study aims to assess the feasibility and safety of robot-assisted radical prostatectomy (RARP) using the Toumai™ robotic system in a tertiary center.

Who can participate?
Patients aged 18 years and over with localized prostate cancer who want to be treated with robotic radical prostatectomy

What does the study involve?
Patients are treated with robot-assisted radical prostatectomy using the Toumai™ MT1000 platform.

What are the possible benefits and risks of participating?
Prostate cancer surgery carries specific risks but participating in the study does not increase those risks as it is a validated technology with CE mark approval.

Where is the study run from?
Clinica Alemana de Santiago (Chile)

When is the study starting and how long is it expected to run for?
December 2024 to August 2025

Who is funding the study?
Clínica Alemana de Santiago (Chile)

Who is the main contact?
Hugo Otaola, Hugotaolarca@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
ID 1052

Study information

Scientific Title
Introducing the Toumai™ System for robot-assisted radical prostatectomy: a prospective feasibility and safety study in a tertiary care center (TouRARP)

Acronym
TouRARP

Study objectives
Assess the feasibility and safety of robot-assisted radical prostatectomy (RARP) using the Toumai™ robotic system in a tertiary center. Furthermore, the researchers aimed to describe its key features to guide centers considering this technology

Ethics approval required
Ethics approval not required

Ethics approval(s)

Study design
Prospective single-center case series

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Robot-assisted radical prostatectomy with Toumai™ robotic system

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Toumai™ robotic system (MT 1000)

Primary outcome(s)
1. Feasibility, defined as the successful completion of surgical procedures without needing to convert to conventional techniques at the end of surgery
2. Safety evaluated through documentation of intraoperative or postoperative complications at 1 month of follow-up

Key secondary outcome(s))
Perioperative variables associated with this new robotic platform, measured using the Clavien-Dindo classification at 1 month of follow-up

Completion date
31/08/2025

Eligibility

Key inclusion criteria
Localized prostate cancer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
Male

Total final enrolment
50

Key exclusion criteria
Patients for whom all perioperative information was not available were excluded from the analysis

Date of first enrolment
04/12/2024

Date of final enrolment
28/08/2025

Locations

Countries of recruitment
Chile

Study participating centre
Clínica Alemana
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7650568

Sponsor information

Organisation
Clínica Alemana

ROR
https://ror.org/028ynny55

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Clínica Alemana de Santiago

Alternative Name(s)
Clínica Alemana

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
Datasets generated during de current study will be available upon request from Hugo Otaola-Arca (hugotaolarca@hotmail.com)

IPD sharing plan summary
Available on request