

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/09/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/09/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

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Additional identifiers

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

Av. Manquehue Nte. 1410

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Región Metropolitana

Santiago

Chile

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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