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

Submission date	Recruitment status	Prospectively registered
28/08/2025	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
01/09/2025	Completed	Results
Last Edited	Condition category	Individual participant data
01/09/2025	Cancer	[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

#### Contact name

Dr Hugo Otaola Arca

#### **ORCID ID**

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## Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

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

## 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 Vitacura Región Metropolitana Santiago Chile 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

## Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes