Prospective Clinical Utility Study for the NaPi2b (67) Assay in Serous Ovarian Cancer

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To evaluate the clinical utility of the NaPi2b (67) Assay for use in the detection of NaPi2b in formalin-fixed, paraffin-embedded (FFPE) serous ovarian carcinoma tissue to determine patient eligibility for treatment with XMT-1536.

Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms female benign
Study type	Interventional

Summary

ID

NL-OMON53260

Source
ToetsingOnline

Brief title
TSUNAMI UP-NEXT Clinical Utility Study Protocol

Condition

- Reproductive neoplasms female benign

Synonym
ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Leica Biosystems Newcastle
Source(s) of monetary or material Support: industry sponsored trial by Mersana Therapeutics Inc.,Mersana Therapeutics Inc.

Intervention

Keyword: NaPi2b (67), Ovarian Cancer, Tsunami, UP-NEXT

Outcome measures

Primary outcome

Acceptance criteria are established by Mersana and analysis will be conducted

by Mersana.

Secondary outcome

N/A

Study description

Background summary

The purpose of this study is to prospectively screen formalin-fixed, paraffin-embedded (FFPE) serous ovarian carcinoma tissue samples collected from the Mersana Therapeutics study MER-XMT-1536-3 (UP-NEXT) with the NaPi2b (67) Assay. This assay is being used to determine the NaPi2b status, a requirement for determining patient eligibility in MER-XMT-1536-3 (UP-NEXT).

Study objective

To evaluate the clinical utility of the NaPi2b (67) Assay for use in the detection of NaPi2b in formalin-fixed, paraffin-embedded (FFPE) serous ovarian carcinoma tissue to determine patient eligibility for treatment with XMT-1536.

Study design

In this clinical utility study, the anonymized serous ovarian cancer samples will be assessed for NaPi2b status, a requirement for determining patient eligibility in Mersana UP-NEXT Study MER-XMT-1536-3.

Intervention

N/A

Study burden and risks

N/A

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• FFPE tissue block or at least 3 FFPE tissue slides (1 for detecting NaPi2b status, 1 for negative rabbit control, and 1 slide for H&E assessment) of 4-5 µm section thickness received from Mersana collection sites, collected according to Mersana study MER-XMT-1536-3 (UP-NEXT).
• Surgical resections or core needle biopsies (FFPE)
Tissue preparation must meet all slide/sectioning requirements as detailed within the NaPi2b (67) Assay IFU and BOND User Manual:
• Section Thickness (if slides): 4-5 µm
• Slides: Positively Charged, Leica BOND-III Compatible

• Fixative: Formalin Fixed

Exclusion criteria

• Fine Needle Aspirate (FNA) and ascites samples prepared as FFPE cell blocks
• Cytology specimens (FNA, ascites, cell block)
• The specimen is collected at a site which is not covered under Mersana study MER-XMT-1536-3 IRB/IEC review.
• The specimen is a repeat specimen from a patient whose sample has already been included in the study.
• FFPE section thickness is not 4-5 µm
• Slides are not positively charged or are incompatible with BOND-III
• Tissue is not formalin-fixed

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-04-2023
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Generic name:	Leica Biosystems BOND Ready-to-Use Primary Antibody NaPi2b (67)
Registration:	No

Ethics review

Approved WMO Date:	05-06-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL83931.000.23