Usefulness of a combined NLR - CA-125 marker (NLR x CA-125) in the prediction of OHSS in IVF / ICSI patients

Published: 20-10-2010
Last updated: 02-05-2024

To determine the usefulness of a combined NLR - CA-125 marker (NLR x CA-125) in the prediction of OHSS in IVF/ICSI patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive tract disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON34985

Source
ToetsingOnline

Brief title
Combined NLR - CA-125 marker (NLR x CA-125) in IVF / ICSI patients.

Condition

- Reproductive tract disorders NEC

Synonym
ovarian hyperstimulation syndrome in IVF patients

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: via het Sint Franciscus Gasthuis;Rotterdam

Intervention

Keyword: CA-125, IVF, NLR, OHSS

Outcome measures

Primary outcome

Occurrence of OHSS after IVF/ICSI

Secondary outcome

Clinical pregnancy

Study description

Background summary

Recently, Cho et al. (1) described the validity of the combination of the neutrohpil/lymphocyte ratio (NLR) and the serum CA-125 concentration as a diagnostic marker for endometriosis and ovarian tumors, both malignant and benign. In patients with a benign ovarian tumor a significantly higher NLR was found, compared with controls (2.31 versus 1.99).
During IVF / ICSI, serum CA-125 concentations rise and higher CA-125 levels are related to higher clinical pregnancy rates (2).
Ovarian hyperstimulation syndrome (OHSS) is a serious and relatively common complication of IVF/ICSI. Early detection of OHSS after IVF/ICSI is essential for the wellbeing of the patient and for the chances of a successful pregnancy. Both NLR and CA-125 are increased in IVF/ICSI patients with and without OHSS. However, NLR and CA-125 levels are substantially higher in OHSS patients compared with IVF/ICSI patients without OHSS (pilot study Sint Franciscus Gasthuis). Determination of the combined NLR and CA-125 concentration might predict OHSS. Especially differences in the early phase of the IVF/ICSI treatment could have clinical value. Therefore, NLR and CA-125 concentrations are measured at the time of oocyte pickup (OPU) and in the midluteal phase.

1) Cho, S., Cho, H., Nam, A., Kim, H.Y., Choi, Y.S., Park, K.H., Cho, D.J. and Lee, B.S. Neutrophil-to-lymphocyte ratio as an adjunct to CA-125 for the diagnosis of endometriosis. Fertility and Sterility 2009; 90: 2073-2079.

2) Baalbergen A, Janssen JW, van der Weiden RMF. CA-125 levels are related to the likelihood of pregnancy after in vitro fertilization and embryo transfer. Am J Reprod Immunol 2000; 43: 21-24.

A recent study showed that the neutrophil/lymfocyt ratio (NLR) combined with the CA-125 serum concentration is a diagnostic marker for endometriosis. This study also showed that patients with a benign ovarian tumor had significantly elevated NLR (2.31) compared with healthy controls (1.99). To study the prognostic value of the CA-125 serum concentration combined with the NLR in the chance to get pregnant, we must study the NLR in patients with OHSS first. Because it is already known from recent studies that the NLR is significantly higher in patients with a benign ovarian tumor, as well as the CA-125 serum concentration (1).

1) Cho, S., Cho, H., Nam, A., Kim, H.Y., Choi, Y.S., Park, K.H., Cho, D.J. and Lee, B.S. Neutrophil-to-lymphocyte ratio as an adjunct to CA-125 for the diagnosis of endometriosis. Fertility and Sterility, Vol. 90, No. 6, December 2008.

Study objective

To determine the usefulness of a combined NLR - CA-125 marker (NLR x CA-125) in the prediction of OHSS in IVF/ICSI patients.

Study design

Venous serum samples are taken during IVF/ICSI treatment:

1) after insertion of the intravenous line for analgesia prior to OPU (no extra venapuncture).

2) in the midluteal phase (one week after OPU).

Laboratory tests:
- CA-125
- Leucocyte differentiation (NLR)
- CRP
- Ht
- Estradiol

Serum amples are stored at - 70 Celsius.

Study burden and risks

Risk associated with an extra venapuncture.

Contacts

Public
Sint Franciscus Gasthuis

Kleiweg 500
3045 PM
NL
Scientific
Sint Franciscus Gasthuis

Kleiweg 500
3045 PM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

patients wishing to conceive with IVF/ICSI

Exclusion criteria

Patients with endometriosis

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2011
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO

Date:	20-10-2010
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL31185.101.10