

PreOS Study (Preeclampsia open study)

A multicenter, prospective, open, non-interventional study evaluating the influence of the angiogenic biomarkers sFlt-1 and PlGF on decision-making of physicians in pregnant women with suspicion of preeclampsia¹

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Introduction

Preeclampsia may be caused by an imbalance of angiogenic factors. It has been demonstrated that high serum levels of sFlt-1, an anti-angiogenic protein, and low levels of PlGF, a pro-angiogenic protein, predict subsequent development of preeclampsia. The sFlt-1/PlGF ratio was markedly elevated before the onset of clinical preeclampsia.^{2,3}

Roche Professional Diagnostics has developed the first fully automated Elecsys® sFlt-1 and PlGF immunoassays for use on the **cobas** modular platform currently CE IVD approved for “aid in diagnosis of preeclampsia”.

The clinical utility of the sFlt-1/PlGF ratio in guiding decisions on management of patients with suspicion of preeclampsia in clinical routine is not yet established. There is a need for a study to demonstrate the value of the fully automated Elecsys® sFlt-1/PlGF test of Roche in clinical decision making with regard to patient management by hospitalization or ambulant treatment, looking at maternal and fetal outcomes.

Key conclusion

PreOS is the first observational clinical multicenter study to demonstrate the clinical utility of fully automated Elecsys® sFlt-1/PlGF maternal blood testing with regard to clinical decision making in pregnant women with suspicion of preeclampsia.

The study will provide evidence on the added value of sFlt-1/PlGF testing in indeterminate cases of suspected preeclampsia and guide appropriate patient management with regard to hospitalization, delivery and other clinical procedures in real world clinical practice for improved outcomes.



Life needs answers

Study design

PreOS is a multicenter, prospective, open-label, non-interventional study, recruiting 150 pregnant women with suspicion of preeclampsia from gestational week 24+0 days until delivery at five investigational sites in Germany and Austria.

Primary study objectives

To assess the influence of the fully automated Elecsys® sFlt-1/PIGF test of Roche on the decision making of the physician to hospitalize patients with suspicion of preeclampsia.

Secondary study objectives

To assess the influence of the sFlt-1/PIGF ratio on the decision making of the physician to induce delivery and further diagnostic and therapeutic procedures.

Inclusion criteria

Pregnant women 18 years who present with suspicion of preeclampsia, in gestational week 24+0 days, for whom determination of the sFlt-1/PIGF ratio is planned (but not yet carried out), with written informed consent.

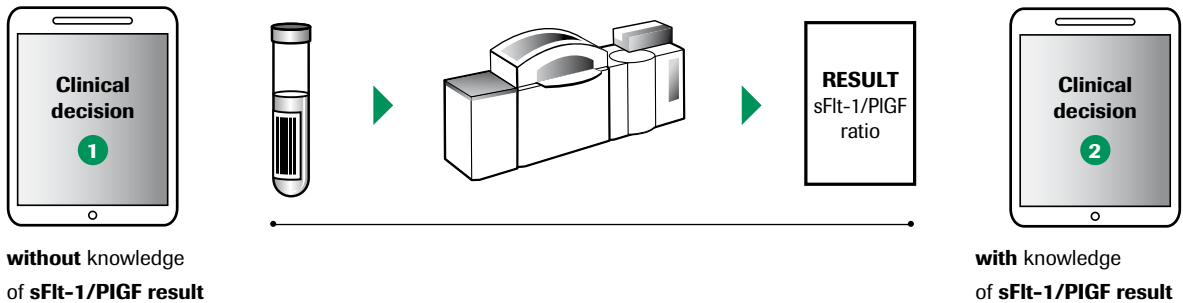
Suspicion of clinical diagnosis of preeclampsia based on one or more of the following criteria:

- New onset of elevated blood pressure
- New onset of hypertension
- Aggravation of pre-existing hypertension
- New onset of protein in urine
- New onset of proteinuria
- Aggravation of pre-existing proteinuria
- One or more other reason(s) for clinical suspicion of preeclampsia

Exclusion criteria

Women with manifest preeclampsia, eclampsia or HELLP (hemolysis, elevated liver enzymes, low platelet count) syndrome are excluded from the study.

Study flow



Once a subject is enrolled in the study, medical data except sFit-1/PIGF test result are available to the investigator that will record decisions on the clinical management of the patient using the iPad®.

After receiving the results of sFit-1/PIGF ratio for the subject, the investigator can revise or confirm the clinical management decisions using the iPad®.

Study location

The study was performed in 5 obstetrics department in Germany and Austria.

Site/location

Universitätsfrauenklinik Leipzig, Germany

Frauenklinik der TUM, Munich, Germany

Medizinische Universität Innsbruck, Austria

Universitätsklinikum Jena, Germany

Frauenklinik Frankfurt, Germany

Acknowledgement

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Thanks also to the Roche colleagues for their dedicated support.*

Abbreviations

sFit-1 = soluble fms-like tyrosine kinase-1

PIGF = placental growth factor

HELLP = Hemolysis, Elevated Liver enzymes and Low Platelets

References

- 1 Hund M et al. poster presented at the 18th World Congress on Controversies in Obstetrics, Gynecology and Infertility (COGI), Vienna, Austria, 24–27 October 2013
- 2 Verlohren S et al. 2012. *Am J Obstet Gynecol* 206(58), e1–8
- 3 Verlohren S et al. 2010. *Am J Obstet Gynecol* 202(161), e1–11

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