

Novel clinical triage protocol for threatened miscarriages saves pregnancies

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A study conducted by clinicians from KK Women's and Children's Hospital (KKH) and researchers at the Nanyang Technological University, Singapore (NTU), which evaluated and demonstrated the safety and effectiveness of a KKH-developed novel clinical protocol to screen and triage women with threatened miscarriages, has been

published in the journal, *Scientific Reports*.

In the novel clinical protocol, a single serum [progesterone](#) (a blood test to measure the progesterone level in the body) is used to screen and triage women with threatened miscarriages, thereby guiding clinicians in the stratification and management of these patients. This screening protocol identified 240 high-risk pregnancies with a low progesterone level, with subsequent treatment and preventing a [miscarriage](#) in 70 (29.2%) high-risk pregnancies. 847 (77.9%) low-risk women with high progesterone level avoided the use of progestogens, with a miscarriage rate of less than 10%. This safe and effective clinical protocol has revolutionised the management of women with threatened miscarriage, and can be readily adapted for use in other healthcare institutions with only a single blood test.

Threatened miscarriage, which presents as vaginal bleeding in early pregnancy, affects up to 25% of all pregnancies, and 15% to 20% of threatened miscarriages progress to spontaneous miscarriage. There is currently no [effective treatment](#) available for a threatened miscarriage. However, progestogens, a medication to support pregnancies, in particular those with low progesterone levels, is given routinely by many healthcare institutions in the world including KKH, prior to the implementation of the novel clinical protocol.

Associate Professor Tan Hak Koon, Chairman, Division of Obstetrics and Gynaecology, KKH, said, "As the largest maternity hospital in Singapore, KKH manages an average of about 15 threatened miscarriages in a day, and therefore this validated novel clinical protocol marks a significant milestone for us, propelling us towards our goal of improving the [health outcomes](#) for generations of [pregnant women](#) and their babies. With this effective and safe screening and triage clinical protocol, pregnant women with risk of a threatened miscarriage can be detected early, receive timely intervention including anticipatory

guidance, counselling, medical treatment, or monitored closely for adverse pregnancy outcomes throughout the rest of the pregnancy."

This study was recently published in the journal, *Scientific Reports*, and involved a total of 1,087 pregnant women presenting with a threatened miscarriage at the Urgent O&G Centre, KKH—Singapore's largest academic medical centre specialising in women's and children's health. The strength of this study is that it is the largest prospective cohort study of a novel clinical protocol.

In the study, pregnant women with threatened miscarriages were triaged and stratified into two groups—the high-risk group (77.9%) consists of pregnant women who had serum progesterone ≤ 35 nmol/L were stratified in the low-risk group (22.1%). Women in the high-risk group were treated with oral progestogen, given counselling and monitored closely. Women in the low-risk group were conservatively managed through counselling and reassurance with no oral progestogen treatment. All pregnant women were reviewed in a KKH clinic two weeks later and follow up until week 16 of gestation to determine the pregnancy outcome.

23.1% of pregnant women experienced a spontaneous miscarriage before 16 weeks of pregnancy. Among the women who received progesterone treatment, 29.2% of women in the high-risk group and 90.4% of women in the low-risk group continued with their pregnancies beyond 16 weeks. Miscarriages despite progesterone treatment may be attributable to other causes, such as chromosomal abnormalities, infections and maternal diseases, regardless of serum progesterone levels.

Co-author of the study, Dr. Ku Chee Wai, Division of Obstetrics and Gynaecology, KKH, said, "The novel clinical [protocol](#) in the study has been established to be effective and accurate in predicting pregnant

outcomes at 16 weeks of gestation amongst the two risk- stratified groups. Through early intervention, we were able to prevent a miscarriage in about 70 (29.2%) pregnancies. We have also avoided the use of progestogens in 847 (77.9%) pregnant women, without increasing their risk of miscarriage. This further reduces the potential side effects or adverse outcomes associated with medical therapy, with increased financial savings for the patient. Women with normal progesterone levels are further reassured that they will have a high chance of having a successful pregnancy, leading to less anxiety and a positive pregnancy experience."

KKH and NTU had also conducted another related study, published earlier this year. The KKH-led study, 'Characterisation of serum progesterone and progesterone-induced blocking factor (PIBF) levels across trimesters in healthy pregnant [women](#)', published in the journal, *Scientific Reports*, in March 2020, showed that serum progesterone and PIBF levels play important roles in healthy pregnancies, with increasing progesterone and PIBF concentrations seen in advancing trimesters and increasing gestational age. This may lead to the development of reference ranges for progesterone and PIBF to predict the viability in all three trimesters of [pregnancy](#), and support further research on the role of progesterone and PIBF in the maintenance of healthy pregnancies.

More information: Thiam Chye Tan et al, Novel approach using serum progesterone as a triage to guide management of patients with threatened miscarriage: a prospective cohort study, *Scientific Reports* (2020). [DOI: 10.1038/s41598-020-66155-x](https://doi.org/10.1038/s41598-020-66155-x)

Mark Kit Lim et al. Characterisation of serum progesterone and progesterone-induced blocking factor (PIBF) levels across trimesters in healthy pregnant women, *Scientific Reports* (2020). [DOI: 10.1038/s41598-020-59452-y](https://doi.org/10.1038/s41598-020-59452-y)

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