

PATIENTS NEEDED FOR RESEARCH STUDY

Estrogen dosing in Turner Syndrome: Pharmacology and Metabolism

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What is Turner Syndrome?

Turner Syndrome (TS) is a common genetic condition affecting only girls. They present with short stature, hence they need growth hormone for growth. They also have abnormal development of the ovaries and need estrogen replacement starting in their teenage years, and continued for life.

Estrogen is necessary for feminization during puberty and for normal bone health. There is a wide variation in the types of estrogens used for replacement, as well as in doses and routes of administration. We propose a study to address which type, what dose and what route of delivery of estrogen are suitable choices in feminizing and sustaining estrogen concentrations in girls/young women with Turner syndrome. These girls/young women must have already achieved their maximal growth and should not be on growth hormone therapy.

What Is Involved In Study?

To accomplish this, we will study girls with TS between the ages of 13 to 20 whom have been off growth hormone for at least 6 months. The study will be done in two parts. In Part 1, girls will receive 3 different estrogen preparations, either by mouth or via a patch for a total of 6 wks. In this part of the study we hope to learn how the body responds to estrogen depending on the dose and route of administration given.

In Part 2, girls with TS will take estrogen for one year, by mouth or via a patch, and the doses will be adjusted during the study depending on the blood levels of estrogen. Progesterone will also be given, to mimic the normal female cycle. We hope to learn how estrogen affects body composition, blood cholesterol levels and other hormones.

Your participation will allow us to understand the best way to replace estrogen as well as to determine the optimal dosing in young women with TS. The use of these preparations is not considered investigational.

The cost of all these studies, including study medications will be free of charge to the families. If you decide to participate, we will pay you \$400 for participation in Part 1 and \$350 for Part 2, to help offset some of the costs of coming to these visits.



The Division of Pediatric Endocrinology & Metabolism
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or contact the NCC Division of Pediatric Endocrinology at Thomas Jefferson University in
Philadelphia, PA at 215-955-1648 or email jlross@nemours.org.

For questions regarding the rights of research participants call Nemours Office for Human Subjects Protection: 904-697-4023 or
Baptist Health Institutional Review Committee: 904-202-2127

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