STUDY INFORMED CONSENT COVER PAGE

Official Title: Randomised Controlled Trial of Two Different Cumulative Dosages of Roaccutane for Cystic Acne

Short Title: Roaccutane 120 mg/kg vs 150 mg/kg for Cystic Acne

Principal Investigator: Prof. Dedee F. Murrell, St George Hospital, Kogarah NSW, Australia

Study Identifier (NCT Number): To be assigned by ClinicalTrials.gov upon registration

Date: 17 October 2000

The St George Hospital
& Community Health Service

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Approval Number: 00/102 Murrell

SOUTH EASTERN SYDNEY AREA HEALTH SERVICE ETHICS COMMITTEE SOUTHERN SECTION

PARENTAL (OR GUARDIAN) INFORMATION AND CONSENT FORM

Title of Project: Cumulative Roaccutane dose and risk of acne recurrence.

Roaccutane is an effective therapy for moderate to severe acne. The medication is typically used in patients who have failed to respond to conventional therapies (i.e. oral antibiotics) or who exhibit acne scarring. Although the majority of patients treated with a course of Roaccutane will have complete clearing of their acne, a small but significant percentage of patients will develop a recurrence of acne over time and require additional therapy. We are performing a study to evaluate the treatment dose of Roaccutane that will limit recurrences of acne.

What does of the study involve?

The study will compare two different cumulative Roaccutane doses and assess the risk of acne recurrences after completion of treatment for at least one year. Approximately 100 patients will be enrolled in the study. Should you choose to permit your child to participate, he/she will be randomized into one of two treatment groups. One group will receive a cumulative Roaccutane dose of 120mg/kg and the other group 150mg/kg. Both of these doses have been shown to result in complete clearing of acne in the majority of cases. Your child will take Roaccutane on a daily basis as prescribed by one of the study dermatologists until he/she reaches the total cumulative dose (typically 4-8 months of treatment). Follow-up visits will be held every six to eight weeks while your child is on Roaccutane, at which time he/she will be evaluated for therapeutic response and side-effects. Photographs will be taken at each visit to assist in monitoring response to treatment. Laboratory evaluations will be performed at each visit as necessary. After completion of treatment, follow-up visits will occur every three months for at least one year. During these visits, your child will be evaluated for a recurrence of his/her acne.

Patients Signature: _____

Possible Benefits
Roaccutane is an extremely effective treatment for acne and is the only therapy available that can potentially cure acne. The majority of patients treated with a course of Roaccutane will experience complete clearing of their acne with prolonged remissions.

Possible Risks
Roaccutane has a well-established side effect profile. Some of the more common adverse effects include:

- Drying of the skin and mucosal surfaces
- Headaches
- Visual disturbances
- Bone stiffness or muscle aches
- An increased susceptibility to sunburn
- Hepatotoxicity. In most cases, liver enzymes return to normal levels by decreasing the dose of Roaccutane or discontinuing therapy
- Elevation of lipid levels (triglyceride and cholesterol)
- Diabetic patients may need more frequent monitoring of blood sugars as levels may become increased while on Roaccutane
- Risk of drug interactions if taking concurrent medications.

Your child will be provided with a patient information sheet that is supplied by the company that manufactures Roaccutane. This information sheet will review the potential adverse effects in more detail. Please feel free to address any concerns that you or your child may have with one of the study physicians. Roaccutane is a safe therapy when used appropriately and in experienced hands.

What will I get out of the study?
Your child's acne should improve significantly after treatment. His/her participation will also assist physicians to choose the most appropriate treatment doses of Roaccutane in the future to give the most benefits with the fewest adverse effects.

Alternatives to Participation
If your child chooses not to participate in this study, or if your child chooses to withdraw from the study, he/she may still receive treatment with a standard course of Roaccutane for management of his/her acne. Other treatment options include oral antibiotics, hormonal therapy, and topical therapies.

Confidentiality and Disclosure of Information
All data generated in the study will be kept confidential so that it will be impossible to identify any patients from the data collected in the trial. The data will be computerized to compile, validate, and report the data.

Patients Signature: _____

The study physician will also write a letter to your child's GP to tell him/her that your child is taking part in a study. The confidentiality of your child's notes is assured and his/her name will not appear in any publications or reports.

Pregnancy

Pregnant or breast-feeding women are not permitted to take part in this study. Roaccutane is a known teratogen and can cause serious risks to a developing fetus. Furthermore, all women of childbearing potential must document a negative pregnancy test prior to initiating treatment with Roaccutane and at 6week intervals throughout the course of treatment. Two effective forms of contraception (i.e. oral contraceptive pill and condoms) must be used for one month before and continued for one month following discontinuation of Roaccutane therapy. A pamphlet outlining contraceptive methods will be provided to you. Abstinence is not a recommended form of contraception and patients wishing to choose this method of contraception must sign a waiver acknowledging the risks involved.

Participation is voluntary

Your child's participation in this study is entirely voluntary: He/she is in no way obliged to participate and, if your child does participate, he/she can withdraw at any time. Whatever you and your child decide, please be assured that it will not affect your child's medical treatment or his/her relationship with medical staff. Termination of your child's participation in the trial may also occur if he/she experiences a serious adverse event(s) or if the study is stopped by the company making Roaccutane or by the authorities approving the conduct of this trial.

Before deciding whether or not to enroll your child in this study, you may wish to discuss the project with a relative or friend or your local health worker.

You and your child will be informed in a timely manner if any new information becomes available which may influence your decision to allow your child to remain in this study.

Further information

When you and your child have read this information, Dr Murrell or Dr Cummins will discuss it with you further and answer any questions that either of you may have. Only sign the Consent Form once you have had a chance to ask your questions and have received satisfactory answers.

If you or your child have questions at any time during the study, feel free to contact Dr Murrell or Dr Cummins at (02) 9350 2543. A copy of this information sheet will be made available for you to keep.

Patients Signature: _____

Complaints
Complaints may be directed to the Ethics Secretariat, South Eastern Sydney Area Health Service Research Ethics Committee (Southern Section), St George Hospital, Gray Street, Kogarah 2217. Telephone: 9350 2986 Fax: 9350 2988. Email: draker@sesahs.nsw.gov.au

Thank you for your interest in this study.

You will be given a copy of this form to keep.

Patient's signature: _____

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SOUTH EASTERN SYDNEY AREA HEALTH SERVICE ETHICS COMMITTEE SOUTHERN SECTION

PARENTAL (OR GUARDIAN) INFORMATION AND CONSENT FORM (continued)

(Title of Project: Cumulative Roaccutane dose and risk of acne recurrence.)

1. I,_____ of _____ agree to permit _____, who is aged _____ years, to participate as a subject in the study described above.

2. I acknowledge that I have read the Information Statement, which explains the aims of the study and the nature of the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this Consent Form, I have been given the opportunity to ask any questions relating to the possible physical and mental harm my child might suffer as a result of participation and I have received satisfactory answers.

4. I understand that I can withdraw my child from the study at any time without prejudice to my or the child's relationship to St. George Hospital.

5. I agree that research data gathered from the results of the study may be published, provided that neither I nor the child can be identified.

6. I understand that if I have any questions relating to the child's participation in this study, I may contact Dr. Murrell or Cummins on telephone at (02) 9350 2543, who will be happy to answer them.

Signature of Parent/Guardian	Signature of Witness
Please PRINT Name	Please Print Name
Date	Nature of Witness
Signature(s) of Investigator(s)	
Please PRINT Name	