

Is Your Child Ready to Quit Smoking Cigarettes?

This study may be an option.

Adolescents may be able to participate if they

- Are 12 to 16 years old and in good health
- Smoke at least 5 cigarettes a day
- Have tried to quit

Your child's study doctor can tell you if your child meets all of the requirements.

Benefits to Your Child for Participating

If your child wants to quit smoking, this study may be an option. Adolescents who participate will receive, at no cost:

- Investigational medication
- Access to study-related smoking cessation counseling
- Study-related check-ups

They will also be making a contribution to medical research.

**Ask About the Adolescent
Smoking Cessation Study**

The Importance of Clinical Studies

Most adult smokers started smoking as adolescents. According to the Centers for Disease Control, in 2005, 23% of adolescents were current cigarette smokers. Many of these adolescents want to quit, but they are addicted. A smoking habit increases lifetime risk of various cancers, especially lung cancer, cardiovascular diseases, and respiratory diseases. Clinical studies that may identify ways to help adolescents quit smoking could improve the health and save lives of many Americans.

To find out if your child qualifies, please call



Adolescent Smoking Cessation Study

Help Your Child Try to Quit

**A New Research Study
for 12- to 16-Year-Olds**

What Is the Adolescent Smoking Cessation Study?

This is a new research study for adolescents who are 12 to 16 years old that want to quit smoking.

The Adolescent Smoking Cessation Study is examining whether or not an investigational medication, in conjunction with counseling, can be used as an aid to help adolescents stop smoking. The medication is called “investigational” because it is not FDA approved to help people under 18 years old stop smoking.

Recently, a study was conducted in which 70 adolescent smokers (12–16 years old) were treated with this same investigational medication. This study was performed to better understand blood levels and toleration of the drug in this population. That study demonstrated that the investigational medication was well tolerated by these adolescents. The Adolescent Smoking Cessation Study will be expanded to enroll 300 adolescents 12 to 16 years old.

What Should I Expect if My Child Participates?

Before the start of the study, all areas of the study will be explained thoroughly to you, and any questions that you or your child have will be addressed. Additionally, an ethics committee will review and continually monitor the study with your child’s best interest and protection in mind. Once you voluntarily provide your consent, your child will become a study participant and will be given a unique identification number that will keep his or her study information confidential.

Adolescents who join the study will attend visits during the course of just over 1 year (56 weeks). There will be a total of 23 office visits and 4 telephone contacts. During their participation, adolescents will receive either the investigational medication or placebo (a pill that contains no active medication).

If your child enrolls into the study, he or she will be randomly assigned to take a certain dose of study medication based on his or her weight. There are 3 possible study medication groups:

- Full-strength dose of the investigational medication
- Half-strength dose of the investigational medication
- Placebo

All study medications are in pill form and look identical. All participants in the study are expected to take their study pills for the first 12 weeks of the study.

There will be weekly clinic visits for the first 12 weeks and a 9-month nontreatment follow-up period. Participants will have access to smoking cessation counseling in addition to the study treatment.

Participants will stop study medication after 12 weeks, regardless of whether or not they have stopped smoking. Participants that enter the study and are not able to quit smoking will be encouraged to stay in the research study, to continue taking study medication, continue participation in the counseling program, and to keep trying to quit. In other words, the inability to quit smoking will not require that a participant withdraw from this study. However, you are free to withdraw from the study at any time. In most states, participants younger than 18 years old will need to have your permission to join the Adolescent Smoking Cessation Study.

Each study site team specializes in conducting clinical studies and will ensure that all of the study visits run smoothly. As a study participant, your child will be assigned a study coordinator—a valuable resource who will be with your family every step of the way.