Study Title: A Randomized Controlled Trial of Oral Curcumin for the Treatment of CMC Arthritis

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Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Medical Record # _____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

This study is being funded by the American Society for Surgery of the Hand.

Key Information About This Research Study

Principal Investigator:	Brent DeGeorge MD, PhD Department of Plastic Surgery University of Virginia 415 Ray C. Hunt Dr. Charlottesville VA 22903 Phone: 434-982-4263 Email: bd6u@virginia.edu
Sponsor:	American Society for Surgery of the Hand

You are being asked to take part in a research study. You do not have to take part in this study.
You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, healthcare providers, or others before you make a decision.

What is the purpose of this study?

The purpose of this study is to investigate if oral Curcumin (Turmeric) is safe and effective as a treatment for thumb arthritis (also known as thumb carpometacarpal (CMC) arthritis). Turmeric has been effective in treating other forms of arthritis but has not yet been tested in people with thumb arthritis.

If you choose to take part in this study, you will have up to 6 study visits that last about an hour each. You will be randomly assigned to take either turmeric or a matching placebo at home for 4 weeks followed by a 2-

week washout period (when the study drug or placebo leaves your body). You will then cross over to the second assignment, which is the study drug you have not taken. You will answer questionnaires and if you are a female of childbearing potential, have a pregnancy test before you receive the study drug. You will have labs drawn at your study visits.

The oral curcumin (turmeric) used in this study is available over the counter, and many people have taken it as a supplement. Taking curcumin (turmeric) as a treatment for CMC arthritis has not been approved by the FDA and is investigational.

You are being asked to take part in this study because you have thumb carpometacarpal (CMC) arthritis.

Why would you want to take part in this study?

You might like to take part in this study because you will receive treatment that may help your CMC arthritis pain. The information learned in this study may benefit people with CMC arthritis in the future.

Why would you NOT want to take part in this study?

You may not want to take part in this study because the study drug used in this study is investigational and has not been approved by the FDA. The study drug used in this study may have side effects, which are discussed later in this form.

You might not want to take part in this study because the study requires research visits and two blood draws.

If you are a female, you may not want to take part in the study if you are unwilling to use birth control during the study and for 30 days after the last day of study drug use.

If you are a male, you may not want to take part in the study if you do not wish to use birth control during the study and for 90 days after the last day of study drug use. You are also asked not to donate sperm during this timeframe. Acceptable methods of birth control are covered later in this form.

What will I have to do if I take part in this study?

Full details of all the procedures are found later in this form.

If you take part in this study, you will:

- Complete questionnaires
- Visit the UVA Hand Clinic up to 6 times. Each visit will last about 1 hour.
- Have your vital signs including heart rate and blood pressure taken.
- Have pregnancy testing (blood and urine) (if applicable)
- Have blood drawn for labs
- Have your medical history taken to see if you qualify for the study.
- Take study drug at home.

- At each visit we will review your current medications and ask you about any side effects you may have experienced, and ask you questions about how the study drug makes you feel.

How many people will take part in this study?

Up to 100 people will be in this study at UVA.

How long will this study take?

Your participation in this study will require 6 study visits over 12 weeks. Each visit will last about 1 hour.

What will happen if you are in the study?

SCREENING

Visit 1 *(Day -14 to 0. This visit will last about 1 hour)*

If you agree to participate, you will sign this consent form before any study-related procedures take place. Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate. These include the following:

- Review of your medical history and current medications.
- Vital signs including heart rate and blood pressure.
- You will be asked to provide about 1 teaspoon of blood for a serum pregnancy test (if applicable).
- You will be asked to provide about 1 teaspoon of blood for tests that measure your blood cells, how your blood clots, and levels of chemicals in your blood.

If these tests show you are eligible, you will return to the clinic within 7 days to begin study intervention.

RANDOMIZATION (BASELINE) and STUDY TREATMENT

Visit 2 (Day 0*) This visit will last about an hour and a half*

You will be randomly assigned (like the flip of a coin) to 1 of 2 study treatment groups. You have an equal chance of being assigned to any one of the groups. You will not be able to find out which one you got (the real drug or the placebo) until the study is done. If your doctor needs to know, the people doing this study can find out. Neither you nor your doctor can choose which treatment you are assigned. Neither you nor your doctor will know which study treatment you will get until the study is done. But if your doctor needs to know, the people doing this study can find out.

The difference between the two groups is the timing of when you will be asked to take the oral curcumin (Turmeric) or placebo, as shown in the table below. From this point on, we will refer to both turmeric and the placebo as “the study drug.”

GROUP 1: Curcumin (turmeric) 500mg twice daily for four weeks followed by placebo twice daily for four weeks

GROUP 2: Placebo twice daily for four weeks followed by Curcumin (Turmeric) 500mg twice daily for four weeks

***A placebo is a harmless substance that looks like the study drug, but which should have no effect.**

You will receive the study drug and begin taking it twice a day by mouth, about 12 hours apart for four weeks (28 days). You will record each dose in the study medication log that is with your study drug. If you miss any dose, you will record the missed dose in the medication log.

During this clinic visit the following study procedures will take place:

- Review of your medical history and current medications.
- Vital signs including heart rate and blood pressure.
- The study doctor will complete a physical exam.
- You will be asked to provide about 1 teaspoon of urine for a urine pregnancy test.
- You will be asked to complete several questionnaires that will ask about your pain level, quality of life, and activity level. These may be done in the office using a provided tablet computer, or if you prefer, you may be emailed a link to these questionnaires that you may access and complete at home.

Study Visits

Visits 3 and 5 (Days 28 and 70). These visits will last about 1 hour.

During these clinic visits the following study procedures will take place:

- Review of your medical history and current medications.
- Vital signs including heart rate and blood pressure.
- You will be asked to provide about 1 teaspoon of blood for tests that measure your blood cells, how your blood clots and levels of chemicals in your blood.
- The study doctor will complete a physical exam at Visit 5.
- You will be asked to complete several questionnaires that will ask about your pain level, quality of life, and activity level. These may be done in the office using a provided tablet computer, or if you prefer, you may be emailed a link to these questionnaires that you may access and complete at home.

*Visits 4 and 6 (Days 42 and 84) will be telephone visits***.*** These visits will last about 10 minutes**.**
During these telephone visits the following study procedures will take place:
Review of your medical history and current medications.
You will be asked to come to clinic provide about 1 teaspoon of urine for a urine pregnancy test at Visit 4 (ONLY if you are a female who has had menses at least once in the previous 48 months and are not menopausal).

Study Schedule

Visit	Visit 1 Screening[1]	Visit 2 Baseline	Visit 3 (Arm 1) Washout Period Begins	Visit 4 (Arm 1) Washout Period Ends	Visit 5 (Arm 2) Washout Period Begins	Visit 6 (Arm 2) Washout Period Ends	Early Termination Visit
Study Day	-14 to 0	0	28 ± 2	42 ± 2	70± 2	84 ± 2	
Informed Consent	X						
Review study eligibility/ Medical History	X						
Blood Pregnancy test (women of childbearing potential)	X			X			
Urine Pregnancy Test (if applicable)		X		X			
Randomization		X					
Study Drug Dispensed		X	X				
Washout period begins/ Study Medication Collected			X		X		X
Washout period end				X		X	X
Vital Signs	X		X		X		X
Physical Exam	X				X		X
Blood testing	X		X		X		X
VAS Pain Score		X	X		X		X
SANE Score		X	X		X		X
Patient Reported Outcome Measures		X	X		X		X
Concomitant Medication	X	X	X	X	X	X	X
Phone Call				X		X	
Adverse Events	X	X	X	X	X	X	X

[1] Screening may take place within two weeks of baseline to allow for results of blood and pregnancy testing.

END OF STUDY:

After you have completed the study, you will no longer receive the study drug or placebo. You will be referred to your primary care provider/or specialist for clinical care.

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You must attend each study visit.
- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Ensure that the study drug is taken as instructed, keep it in a safe place away from children, return any unused study drug at each visit, and report any lost or missed capsules.
- Ensure that the study drug is taken only by you.
- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to the curcumin (turmeric) include:

Likely

- Bleeding/coagulation issues
- Nausea
- Diarrhea
- Abdominal pain or bloating
- Indigestion
- Vomiting
- Cough

Less Likely

- Swelling
- Dizziness

- General body pain
- Headache
- Dry mouth
- Skin rash

Rare but Serious

- Liver injury

Risks of having your blood drawn:

Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

Risks of Sharing the Drug

Do not share the study drug with anyone. It is prescribed only for you and could hurt someone else. Keep it out of reach of children and people not able to read or understand the label.

Blood Donation

If you participate in this study it may affect your ability to donate blood. If you have any questions call the organization where you donate blood and talk to one of their nurses.

Risks from Placebo

There is the risk that you will not get either the study drug/device or your normal medicine/treatment so your thumb arthritis pain may get worse.

Risks from Completing Questionnaires

- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.
- Some of the questions asked may make you angry, emotionally upset or stressed out now or at a later time. If this occurs, you may contact the following person for help: Study Team Member. If you do not wish to answer a question, you may skip it and to the next question.

Risks for women:

Pregnancy and Contraception

The drug(s) used in this study can harm an unborn or nursing baby. Therefore, you cannot be in this study if you are pregnant or nursing a baby. A pregnancy blood test will be done about **7** days before starting this study if you are a woman able to become pregnant. You MUST NOT become pregnant while on this study or for up to 30 days after your last dose of drug.

You and your partner must use an approved form of birth control during this study. Examples of birth control you may use are:

- Norplant
- IUD (intrauterine device)
- Sterilization
- Depo-Provera
- Birth Control Patch

The birth control methods listed below are less effective. They may be used if combined with other birth control methods.

- Condoms
- Jellies or foam
- Cervical cap
- Diaphragm
- Sponge

Ask your doctor for more details about the proper birth control method for you. If you become pregnant during this study, you must tell your doctor right away. Your doctor will discuss your treatment and the effect on the pregnancy.

Risks for men:

We do not know the effects of these drugs on male sperm. If you are a male, you should not father a baby while you are in this study and for 90 days after your last dose of the drug. You should use effective birth control including condoms or sterilization. You should also not donate to a sperm bank during this time. To do so may hurt your unborn baby. You must use an effective method of birth control during this time.

If your partner becomes pregnant during this study or for 90 days after the study ends you must tell the study team right away.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You will not directly benefit from being in this study. Possible benefits include potential pain relief. In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include standard of care for thumb joint arthritis to include medication and/or surgery.

If you are an employee of UVA your job will not be affected if you decide not to participate in this study.
If you are a student at UVA, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will be paid up to $200 by check for being in this study. You will be paid $100 after you complete the first treatment, and $100 after you complete the second treatment. You should receive your check a few weeks after you complete the study. The compensation payment may be reported to the IRS as income.

By agreeing to be in this study, you are donating your blood and bodily fluids for research, and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance:

- Laboratory Testing
- Pregnancy tests
- Vitals signs
- Physical Exam
- Study Drug
- Questionnaires

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required. You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include:

a) Your study physician is concerned about your health.
b) Your disease gets worse.
c) The side effects of the treatment are too dangerous for you.
d) New information shows the treatment will not work or is not safe for you.
e) You do not follow your doctor's instructions.

If you decide to stop being in the study, we will ask you to let us know as soon as possible. You will be required to return all unused study drug capsules, as well as all empty containers as soon as possible. Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth.
- Social Security number ONLY IF you are being paid to be in this study.
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results.
- People or groups that oversee the study to make sure it is done correctly.
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study.
- Tax reporting offices (if you are paid for being in the study).
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study. Information obtained from you during this study will not be used in future research.

A description of this clinical trial will be available on *http:// www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

Please contact the Principal Investigator listed earlier in this form to:

- Obtain more information about the study.
- Ask a question about the study procedures or treatments.
- Report an illness, injury, or other problem (you may also need to tell your regular doctors).
- Leave the study before it is finished.
- Express a concern about the study.

Principal Investigator: Brent DeGeorge MD, PhD
Department of Plastic Surgery-University of Virginia
Address: 415 Ray C. Hunt Dr. Charlottesville VA 22903
Telephone: 434-982-4263

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-2620

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the UVA Study Tracking Number (at the bottom of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

Would you like the study team to communicate with you by email or text message?

If you choose to communicate with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, UVA cannot control this potential loss of privacy but we want to tell you about this possible risk.
You do not have to agree to communicate with the study team by email or text message to be in this study. If you agree to texting or emailing, the study team will collect your phone and /or email address from you that you would like them to use to contact you. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

You do not have to agree to use email or text message to be in this study.
PLEASE INDICATE YOUR CHOICE BELOW:

Yes_____ I agree to be contacted by email or text.
If you agree to texting or emailing, the study team will collect your phone and /or email address that you would like them to use. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

No_____ I DO NOT agree to be contacted by email or text.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form, it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult (***To be completed by participant if 18 years of age or older.)***

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Person Obtaining Consent

By signing below, you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Notification of My Health Care Provider

Please indicate below whether you want us to notify your health care provider that you have agreed to take part in this study.

_____ Yes, I want the study doctor to notify my health care provider that I have agreed to take part in this study.

Health Care Provider Name:
Health Care Provider Address:
Study team will send a copy of the consent form to the health care provider.

_____ No, I do not want the study doctor to notify my health care provider that I have agreed to take part in this study or I do not have a health care provider.

Leaving the Study Early

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.

The follow up information will be collected by:

- Obtaining information from my medical records
- Phone call ONCE
- Sending me surveys/ questionnaires ONCE
- In person follow up visit. ONCE – Safety labs to be drawn, return study drug, study team will ask about reason for early termination.

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Consent From Adult (***To be completed by participant if 18 years of age or older.)***

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Person Obtaining Consent

By signing below, you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE