Clinical Trials at UChicago Medicine: Innovation in Bladder Cancer Treatment

As one of the premier academic medical centers in the country, the University of Chicago Medicine frequently serves as a participating or leading site for innovative clinical trials. Through these unique trials, our investigators and patients contribute to groundbreaking research into treatment for some of today's most challenging diseases, including bladder cancer.

The Section of Urology is currently accepting patients for two open clinical trials:

1. Have Undergone Transurethral Resection of Bladder Tumor
   - The purpose of this study is to test an experimental vaccine called vesigenurtacel-L (HS-410) given either after standard BCG regimen or at the same time as standard BCG to determine if HS-410 can reduce or delay bladder cancer recurrence. BCG is an FDA-approved vaccine for the treatment of bladder cancer.
   - In Phase I, patients received up to a total of 10 low doses of HS-410. The vaccine was administered once a week in two low-dose cycles and then once a month for three months. This phase is now complete.
   - In Phase II, patients continuing to receive BCG therapy will receive up to 21 doses of either low dose HS-410, high dose HS-410 or placebo. Patients not receiving BCG therapy will receive 21 doses of high dose HS-410. The vaccine or placebo will be administered on a regimented schedule over a period of 29 weeks, followed by three weekly doses four months later.
   - This clinical trial provides travel reimbursement to patients.

2. Who Have Failed BCG Therapy and Refused Cystectomy
   - This treatment is for patients with high-grade, non-muscle invasive bladder cancer who have recurrent disease despite traditional BCG therapy and who have refused cystectomy.
   - The lead investigator in this trial at UChicago Medicine is Norm Smith, MD, is a co-PI at UChicago Medicine, and the national principal investigator is Gary Steinberg, MD.
   - In Phase I, patients received up to a total of 15 low doses of HS-410. The vaccine was administered once a week in and kill cancer cells that also selectively expresses the human cytokine GM-CSF to induce a systemic anti-tumor immune response, is safe and effective.
   - The purpose of this study is to test an experimental vaccine called vesigenurtacel-L (HS-410) given either after standard BCG regimen or at the same time as standard BCG to determine if HS-410 can reduce or delay bladder cancer recurrence. BCG is an FDA-approved vaccine for the treatment of bladder cancer.
   - In Phase I, patients received up to a total of 10 low doses of HS-410. The vaccine was administered once a week in two low-dose cycles and then once a month for three months. This phase is now complete.
   - In Phase II, patients continuing to receive BCG therapy will receive up to 21 doses of either low dose HS-410, high dose HS-410 or placebo. Patients not receiving BCG therapy will receive 21 doses of high dose HS-410. The vaccine or placebo will be administered on a regimented schedule over a period of 29 weeks, followed by three weekly doses four months later.
   - This clinical trial provides travel reimbursement to patients.

To learn more about these clinical trials or refer one of your patients for screening, please call 773.702.3080.
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A Phase 1/2, Placebo-Controlled, Randomized Study to Evaluate the Safety, Immune Response and Clinical Activity of HS-410 in Patients with Non-Muscle Bladder Cancer Who Have Undergone Transurethral Resection of Bladder Tumor

The purpose of this study is to test an experimental vaccine called mesengenetic (HS-410) given either after standard BCG-regimens or at the same time as standard BCG to determine if HS-410 can reduce or delay bladder cancer recurrence. BCG is an FDA-approved vaccine for the treatment of bladder cancer.

In Phase I, patients received up to a total of 15 low doses of HS-410. The vaccine was administered once a week for 8 weeks and then every 3 weeks for 4 months. This phase is now complete.

In Phase II, patients continuing to receive BCG therapy will receive up to 21 doses of either low dose HS-410 or placebo. Patients not receiving BCG therapy will receive 21 doses of high dose HS-410. This treatment is for patients with high-grade, non-muscle invasive bladder cancer who have recurrent disease despite traditional BCG therapy and who have relapsed systemically. These patients may qualify for this trial.

In Phase II, patients receiving HS-410 will receive up to 21 doses of either low dose HS-410, high dose HS-410 or placebo. Patients not receiving HS-410 will receive 21 doses of high dose HS-410. The vaccine or placebo will be administered as a regimens schedule over a period of 29 weeks, followed by three weekly doses four months later.

This clinical trial provides trial reimbursement to patients.

The lead investigator in this trial at UChicago Medicine and the national principal investigator is Gary Steinberg, MD.

This clinical trial provides travel reimbursement to patients.

The main purpose of this research study is to evaluate whether CG0070, a conditionally replicating oncolytic adenovirus (serotype 5) designed to preferentially replicate in and kill cancer cells that also selectively expresses the human cytokine GM-CSF to induce a systemic anti-tumor immune response, is safe and effective.

This treatment is for patients who have high-grade, non-muscle invasive bladder cancer who have recurrent disease despite traditional BCG therapy and who have relapsed systemically. These patients may qualify for this trial.

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Ask Us More Questions!

For more information about these clinical trials or to refer one of your patients for screening, please call 773.702.3080.

How to Refer a Patient

Referring a patient to the University of Chicago Medicine, Section of Urology is easy. Our team is available 24/7.

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Ask Us More Questions!

Three of our urologic surgeons are ready resources — we’re always available to talk. At the University of Chicago Medicine, we value collaboration with fellow physicians. Even if you don’t have a specific patient case, call if you have questions. We can also come out and make a presentation about some of our innovative techniques to the physicians in your practice.

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Universities of Chicago Medicine: Innovation in Bladder Cancer Treatment

The Section of Urology is currently accepting patients for two open clinical trials:

A Phase II, Single-Arm, Open-Label Study of CG0070 Oncolytic Vector Regimen for Patients with Non-Muscle Invasive Bladder Cancer Who have Failed BCG Therapy and Refractory Disease

The main purpose of this research study is to evaluate whether CG0070, a conditionally replicating oncolytic adenovirus (serotype 5) designed to preferentially replicate in and kill cancer cells that also selectively expresses the human cytokine GM-CSF to induce a systemic anti-tumor immune response, is safe and effective.

This treatment is for patients with high-grade, non-muscle invasive bladder cancer who have recurrent disease despite traditional BCG therapy and who have relapsed systemically. These patients may qualify for this trial.

In Phase I, patients received up to a total of 15 low doses of HS-410. The vaccine was administered once a week for 8 weeks and then every 3 weeks for 4 months. This phase is now complete.

In Phase II, patients continuing to receive BCG therapy will receive up to 21 doses of either low dose HS-410, high dose HS-410 or placebo. Patients not receiving BCG therapy will receive 21 doses of high dose HS-410. This treatment is for patients with high-grade, non-muscle invasive bladder cancer who have recurrent disease despite traditional BCG therapy and who have relapsed systemically. These patients may qualify for this trial.

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For an adult urology appointment, please call 773.702.1860
For a urologic cancer appointment, please call 773.702.8222...one of our urologic surgeons. Visit our website for more information: http://surgery.uchicago.edu/specialties/urology/

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Innovation and discovery at the core of our mission as clinicians and scientists. In these symbiotic roles, we utilize our newfound discoveries and knowledge to develop pioneering therapies against today’s most challenging diseases, including urologic oncology.

As a testament to that dedication, I’m proud to announce our newest clinical offering—MRI-guided focal laser ablation therapy for prostate cancer. Our clinician-scientists began the clinical trial that made this innovative therapy a reality. Now, millions of men with early-stage prostate cancer can enjoy the many benefits of this less-invasive treatment option that precisely ablates cancer cells without harming nearby structures. Our institution is one of the first in the country to offer this leading-edge therapy.

Our faculty members actively participate in and lead many unique clinical trials like the one mentioned above. I invite you to learn more about these trials, which are currently led by our world renowned urologic specialists and are specifically designed for patients with non-muscle invasive bladder cancer.

If you would like more information about these clinical trials, including each trial’s inclusion criteria, please don’t hesitate to reach out to us. You may also contact 773.702.1860 to contact us at our newfound discoveries and knowledge to develop pioneering therapies against today’s most challenging diseases, including urologic oncology.

NEW, UNIQUE TREATMENT OPTION FOR MEN WITH EARLY-STAGE PROSTATE CANCER

The University of Chicago Medicine has become one of the first medical centers in the country to offer MRI-guided focal laser ablation therapy for men with early-stage prostate cancer.

A NEW WEAPON AGAINST PROSTATE CANCER

Although there are several treatment options for men with early-stage prostate cancer, surgical interventions and radiation therapy are frequently associated with significantly invaded quality of life by the effects of surgery, and with or without excellent long-term outcomes, but are uncontrollable with this approach. MRI-guided focal laser ablation is a treatment strategy that “combines the most attractive elements of treatment modalities of cancer with the most attractive elements of active surveillance (involvement of quality of life),” according to researchers from the University of Chicago Medicine. Performed in tandem by a radiologist and urologic oncologist on an outpatient basis, a patient is given intravenous sedation while lying in an MRI scanner. After injecting a local anesthetic, a small catheter is inserted to deliver a tiny optical fiber, the laser and a cooling device into the diseased prostate. The use of real-time MRI guidance allows accurate positioning of the laser and ablation of the cancerous tissue in the prostate. The image guidance also allows monitoring of the laser’s proximity to nearby tissue, with the goal of protecting critical structures such as the urethra, erectile function nerves and rectal wall.

Why Focal Laser Ablation Therapy?

MRI-guided focal laser ablation combines many potential benefits:
- Minimally invasive nature of focal laser ablation allows procedures to be performed as an outpatient basis.
- There is a lower risk of adverse side effects, such as urinary incontinence, impotence and decreased bowel function compared to surgery or radiation therapy.
- Additional benefits: Laser-based, surgery-related side effect may be performed in the future.
- MRI-guided laser ablation therapy is one of many treatments we offer to patients with prostate cancer. At the University of Chicago Medicine, our experts take a team approach to decide which treatment options are best for each patient, depending on his unique case. Fortunately, patients who meet the following criteria may be candidates for MRI-guided focal laser ablation therapy for prostate cancer:
  - Diagnosed with prostate cancer with a Gleason score of 6 or 7
  - Have no evidence of metastatic disease
  - Able to undergo treatment in an MRI
  - Evidence of cancer on MRI that corresponds with the biopsy findings

The minimally invasive nature of focal laser ablation allows procedures to be performed as an outpatient basis. With much longer follow-up is definitely required, we do feel it may be performed in the future. Why Choose UChicago Medicine?

University of Chicago Medicine experts—urologic oncologist Scott Eggener, MD, and radiologist Aytekin Oto, MD—helped pioneer this cutting-edge procedure. Their work in two clinical trials established the safety and efficacy of laser ablation for prostate cancer.

In the initial Phase I trial (1), Dr. Eggener and Dr. Oto performed the MRI-guided procedure on nine men who were diagnosed with prostate cancer. Each patient was followed for up to six months after their respective procedures, during which time PSA level, International Prostate Symptom scores and Sexual Health Inventory for Men scores were collected. Additionally, a follow-up MRI-guided biopsy of the ablation zone was performed at six months. Results from these follow-up examinations showed cancer in seven patients and Gleason grade 6 cancer in two patients. Additionally, the patients did not suffer any persistent procedural complications, nor report any adverse changes in sexual or urinary function.

Dr. Eggener and Dr. Oto recently completed a 21-patient Phase II trial, funded by the National Cancer Institute. Based on these favorable cancer results, and quality of life results (pending publication), the University of Chicago Medicine has begun offering this procedure.

REFERENCES
New, Unique Treatment Option for Men with Early-Stage Prostate Cancer

The University of Chicago Medicine has become one of the first medical centers in the country to offer MRI-guided focal laser ablation therapy for men with early-stage prostate cancer.

A New Weapon Against Prostate Cancer

Although there are several treatment options for men with early-stage prostate cancer, surgical intervention and radiation therapy are frequently associated with significantly increased quality of life and the risk of sexual side effects. For many patients, less-invasive treatment options that precisely ablate cancer cells without damaging nearby structures are required. Our institution is one of the first in the country to offer this leading-edge therapy.

Our faculty members actively participate in and lead many unique clinical trials like the one mentioned above. I invite you to learn more about these trials, which are currently led by our world-renowned urologic specialists and are specifically designed for patients with non-muscle invasive bladder cancer.

If you would like more information about these clinical trials, including each trial's inclusion criteria, please don’t hesitate to reach out to us. You may also contact us with questions regarding our clinical programs or a particular patient case.

Why MRI-guided Laser Ablation Therapy?

MRI-guided focal laser ablation comes with many potential benefits:

• The minimally invasive nature of focal laser ablation allows procedures to be performed as an inpatient basis.
• There is a lower risk of adverse side effects, such as urinary incontinence and decreased bowel function compared to surgery or radiation therapy.
• Additional complications such as laser-related, surgical or radiation may be performed in the future.

Why Choose UChicago Medicine?

University of Chicago Medicine experts — urologic oncologist Scott Eggener, MD, and radiologist Aytekin Oto, MD — helped perform the initial clinical trial on this new prostate cancer therapy: MRI-guided focal laser ablation.

In the initial Phase I trial (1), Dr. Eggener and Dr. Oto helped perform the MRI-guided procedure on two patients with prostate cancer. Results from these follow-up examinations showed no cancer in seven patients and Gleason grade 4 cancers in two patients. Additionally, the patients did not suffer any serious procedural complications and report any adverse changes in sexual or urinary function.

Dr. Eggener and Dr. Oto recently completed a 27-patient Phase II trial, funded by the National Cancer Institute. Based on these favorable cancer results, and quality-of-life results (see supplement), the University of Chicago Medicine has begun offering this procedure.

Results from these follow-up examinations showed no cancer in seven patients and Gleason grade 4 cancers in two patients. Additionally, the patients did not suffer any serious procedural complications and report any adverse changes in sexual or urinary function.

Dr. Eggener and Dr. Oto recently completed a 27-patient Phase II trial, funded by the National Cancer Institute. Based on these favorable cancer results, and quality-of-life results (see supplement), the University of Chicago Medicine has begun offering this procedure.

New, Unique Treatment Option for Men with Early-Stage Prostate Cancer

The University of Chicago Medicine has become one of the first medical centers in the country to offer MRI-guided focal laser ablation therapy for men with early-stage prostate cancer.

A New Weapon Against Prostate Cancer

Although there are several treatment options for men with early-stage prostate cancer, surgical intervention and radiation therapy are frequently associated with significantly lowered quality of life for the patient, and the risk of serious side effects, including sexual dysfunction, incontinence, and bowel dysfunction. Many men with clinical low-risk prostate cancer are encouraged to do no active surveillance, as aggressive treatment risks excellent long-term outcomes, but are uncomfortable with this approach. MRI-guided focal laser ablation is a treatment strategy that "combines the most attractive elements of treatment intervention of cancers with the most attractive elements of active surveillance [in terms of quality of life]," according to researchers from the University of Chicago Medicine.

Performed in tandem by a radiologist and urologist on an outpatient basis, a patient is given intravenous sedation while lying in an MRI machine. After injecting a local anesthetic, a small cannula is inserted to deliver a tiny optical fiber, the laser and a cooling device into the diseased prostate. The use of real-time MRI guidance allows precise targeting of the laser and ablation of the cancerous tissue in the prostate. The image guidance also allows monitoring of the laser's proximity to nearby tissue, with the goal of protecting critical structures such as the urethra, erectile function nerves and rectal wall.

Why Focal Laser Ablation Therapy?

MRI-guided focal laser ablation comes with many potential benefits:

- The minimally invasive nature of focal laser ablation allows procedures to be performed as an outpatient basis.
- There is a lower risk of adverse side effects, such as urinary incontinence, impotence and decreased bowel function, compared to surgery or radiation therapy.
- Additional procedures (e.g. laser-based, surgery or radiation) may be performed in the future.

Why Choose UChicago Medicine?

University of Chicago Medicine experts – urologist Scott Eggener, MD, and radiologist Aytekin Oto, MD – pioneered this cutting-edge procedure. Their work in two clinical trials established the safety and efficacy of laser ablation for prostate cancer:

- In the initial Phase I trial (1), Dr. Eggener and Dr. Oto performed the MRI-guided procedure on six men with low-stage prostate cancer.
- In the Phase II trial, funded by the National Cancer Institute, 18 men with prostate cancer were treated with this approach. Follow-up exams were performed at six months.
- The patients did not suffer any serious peri-procedural complications nor report any adverse change in quality of life.
- In addition, the patients did not suffer any serious peri-procedural complications nor report any adverse change in quality of life.

Results from these follow-up examinations showed no cancer recurrence in any of the patients who underwent this procedure.

Why Choose UChicago Medicine?

University of Chicago Medicine experts – urologist Scott Eggener, MD, and radiologist Aytekin Oto, MD – pioneered this cutting-edge procedure.


- Prostate Cancer
- Incontinence
- Bladder Cancer
- Enlarged Prostate
- Kidney Cancer
- Testis Cancer
- Pediatric Urology
- Reconstructive Surgery
- Polycystic Kidney Disease

If you have any questions about these programs or regarding a particular patient's care, please don't hesitate to contact us at 773.702.1860 or visit us at surgery.uchicago.edu/specialties/urology.

The University of Chicago Medicine Section of Urology offers the following clinical specialty programs:

- Prostate Cancer
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The Section of Urology is currently accepting patients for two open clinical trials:

1. Phase I/II, Placebo-Controlled, Randomized Study to Evaluate the Safety, Tolerability and Clinical Activity of HD-110 in Patients with Non-Muscle Bladder Cancer Who Have Undergone Transurethral Resection of Bladder Tumor of HS-410 in Patients with Non-Muscle Invasive Bladder Carcinoma

The purpose of this study is to test an investigational vaccine called mesogestectin (HS-410) given either after standard BCG therapy or at the same time as standard BCG to determine if HS-410 can reduce or delay bladder cancer recurrence. BCG is an FDA-approved vaccine for the treatment of bladder cancer.

In Phase I, patients received up to a total of 15 low doses of HS-410. The vaccine was administered once a week for two low-dose cycles and then once a month for three months. This phase is now complete.

In Phase II, patients continuing to receive BCG therapy will receive up to 21 doses of either low dose HS-410, high dose HS-410 or placebo. Patients not receiving BCG therapy will receive 21 doses of high dose HS-410. The vaccine or placebo will be administered as a regimen schedule over a period of 29 weeks, followed by three weekly doses four months later.

This clinical trial provides novel treatment to patients.

The lead investigator in this trial at UChicago Medicine is the national principal investigator is Gary Steinberg, MD.


The purpose of this study is to evaluate whether CG0070, a conditionally replicating oncolytic adenovirus (serotype 5) designed to preferentially replicate in and kill cancer cells that also selectively expresses the human cytokine GM-CSF to induce a systemic anti-tumor immune response, is safe and effective.

This treatment is for patients with high-grade, non-muscle invasive bladder cancer who have recurrent disease despite traditional BCG therapy and who have refractory cystectomy. These patients may qualify for this trial.

As a single-arm open-label study, all participants will receive CG0070. The drug will be administered weekly by bladder instillation for six weeks and potentially for up to one year in patients with a good response.

The lead investigator in this trial at UChicago Medicine is Gary Steinberg, MD.

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