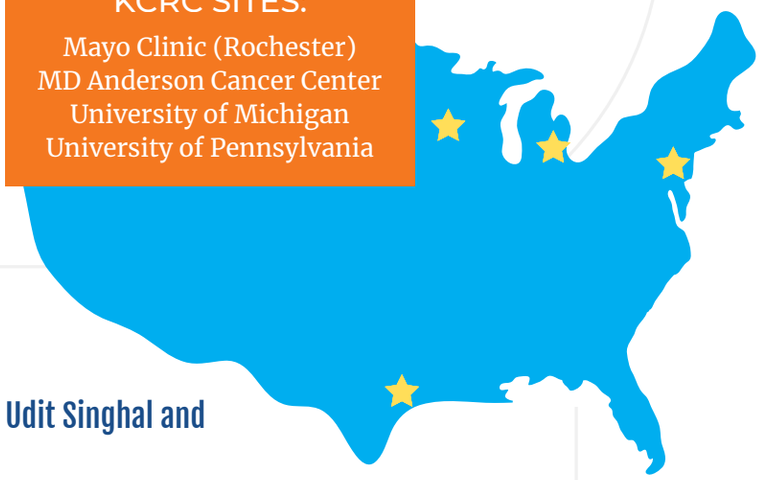
KCRC Kidney Cancer RESEARCH CONSORTIUM

Phase II Trial of Single Agent Belzutifan or Pembrolizumab versus Combination as Neoadjuvant Therapy in Clear Cell Renal Cell Carcinoma (BLAZE)

ENROLLMENT:
54 patients

at

KCRC SITES:
Mayo Clinic (Rochester)
MD Anderson Cancer Center
University of Michigan
University of Pennsylvania



Initiating Sites:

- University of Michigan, Dr. Udit Singhal and Dr. Ulka Vaishampayan
- University of Pennsylvania, Dr. Naomi Haas

Summary: The goal of this clinical research study is to learn if belzutifan alone, pembrolizumab alone, or belzutifan and pembrolizumab in combination given before a total or partial nephrectomy (surgery to remove all or part of a kidney) can help to control locally advanced ccRCC.

Belzutifan is FDA approved and commercially available for the treatment of advanced RCC. Pembrolizumab is FDA approved and commercially available for the treatment of several types of cancer, including RCC. It is considered investigational to give belzutifan alone, pembrolizumab alone, and belzutifan and pembrolizumab in combination before a total or partial nephrectomy to help control locally advanced ccRCC.

Trial Schema

54 eligible patients, randomized into 3 arms:

N = 18	N = 18	N = 18
Belzutifan, 120 mg PO daily for 12 weeks	Pembrolizumab, 200 mg every 3 weeks for 12 weeks	Belzutifan + Pembrolizumab for 12 weeks

Partial or Radical Nephrectomy

Key Criteria

- Clear Cell Renal Cell Carcinoma
- Intermediate High-Risk Disease
- ECOG 0, 1
- Adequate Organ Function
- No prior treatment for RCC prior to study

WOCBP: Women Of Child-Bearing Potential must not be pregnant and must utilize two forms of contraception while on treatment and for 23 weeks after treatment.

Men who are sexually active with WOCBP must agree to utilize acceptable contraception while on treatment and for 31 weeks after.

Drug Frequency: You will take either Belzutifan daily for 12 weeks, Pembrolizumab every three weeks for 12 weeks (4 doses total), or you will take both Belzutifan daily *and* Pembrolizumab every three weeks for 12 weeks.

Costs: Belzutifan and/or pembrolizumab (whichever you are assigned to receive) will be provided at no cost to you during this study.

Clinic Visit Frequency: Patients visit the clinic every 3 weeks until surgery (12 weeks total), and then 30 days after surgery.