

Table 1: UTx Studies Registered on Clinicaltrials.gov

ClinicalTrials.gov Identifier:	Name	Status	Principal investigator	Phase	Sponsor	estimated enrollment	Donor	Start date	Completion date
NCT03307356	Penn Uterine Transplantation for Uterine Factor Infertility Trial (UNTIL)	Active, recruiting	Dr Kathleen E O'Neill			5	Deceased	November 2017	July 2020
NCT02388802	Human Clinical Trial of Uterine Transplantation in the United Kingdom	Not yet recruiting	Dr Richard Smith		Womb Transplant UK;	10	Deceased	January 2017	January 2020
NCT02573415	Uterine Transplantation for the Treatment of Uterine Factor Infertility	Active, recruiting	Dr Andreas Tzakis	Phase 1	The Cleveland Clinic (US)	10	Deceased	October 2015	October 2020
NCT02656550	Uterine Transplantation and Pregnancy Induction in Women Affected by Absolute Uterine Infertility	Active, recruiting	Dr Giuliano Testa		Baylor Research Institute (US)	10	Either living and deceased donors	February 2016	January 2021

NCT02409147	Initiation of a Deceased Donor Uterine Transplantation Program at the University of Nebraska Medical Center	Not yet recruiting	Dr Alexander T Maskin		University of Nebraska (US)	5	Deceased	January 2017	
NCT01844362	Uterus Transplantation From Live Donor	Active, not recruiting	Dr Mats Brännström		Sahlgrenska University Hospital, Sweden	10 (9)	Living	September 2012	April 2018
NCT02637674	Uterine Allotransplantations Using Uterine Grafts From Brain-dead Female Donors (ATU)	Active, recruiting	Dr Tristan Gauthier	Phase 1	University Hospital, Limoges (FR)	10	Deceased	January 2016	January 2022
NCT02741102	Uterine Transplant in Absolute Uterine Infertility (AUIF)	Not yet recruiting	Dr Stefan G Tullius		Brigham and Women's Hospital (USA)	10 (5 donors and 5 recipients)	living	June 2016	January 2023
NCT02987023	Uterus Transplantation From Live Donors With Robotic Assisted Surgery - Gothenburg II (UTX-robot)	Active, recruiting	Dr Mats Brännström	Observational: cohort (Patient registry)	Sahlgrenska University Hospital, Sweden	10 (5 donors and 5 recipients)	Living	November 2016	December 2022
NCT03048396	Acceptance of Uterus Transplantation	recruiting by invitation only.	Dr Sara Brucker		University Women's Hospital Tübingen	10	Living	October 2016	December 2019

Table 2: Study inclusion - exclusion criteria and primary-secondary outcomes

ClinicalTrials.gov Identifier:	Ages Eligible for Study:	Inclusion-exclusion criteria	Primary Outcome Measures:	Secondary Outcome Measures:
NCT03307356	21-40 years	Absolute Uterine Factor Infertility Received counseling regarding alternatives to UTx Intact ovaries and normal ovarian reserve Vaginal length >6 cm Body mass index <30 kg/m ² Fluent in the English Language HPV negative or received vaccination for HPV Willing to comply with screening, protocol and all required procedures In stable committed relationship for ≥3 years Has frozen embryos of sufficient embryo quality/quantity No Previous multiple major abdominal/pelvic surgery No Severe endometriosis No History of hypertension, diabetes mellitus, thrombophilia or other clotting or bleeding disorders, significant heart, liver, kidney or central nervous system disease No History of prior malignancy except for cervical cancer in stage 1a or 1b (must be in remission for 3 years) No History of significant psychiatric illness Allergy, hypersensitivity, or intolerance of expected immunosuppressive agents, heparin or aspirin No Seropositivity for HIV, HBV, HCV, HTLV-1 No current smoker, Chemical and/or alcohol dependency or abuse No Renal abnormalities	Successful engraftment of deceased donor uterus [Time Frame: Assessed 12 months after transplant] Uterus remains in recipient with no complications (i.e. infection or rejection) or any complications that did arise could be successfully treated.	Postoperative complications [Time Frame: Assessed 12 months after transplant] Including but not limited to evidence of damage to surrounding organs/vessels, need for reoperation, thromboembolic event, infection, rejection episodes (clinical and histologic), impaired renal function
NCT02388802	18 - 36 years	Inside of age range Successful oocyte retrieval Normal BMI No significant medical or psychiatric co-morbidities No previous oncology patients <5 years in remission	Transplant success with no clinical, immunological or radiological signs of graft rejection within the first 12 months post-operatively.	Pregnancy rate [TF: 24 months]; live birth rate [TF: 36 months]

NCT02573415	21 -45 years (embryos produced between the age of 21-39)	Hypertension Diabetes Significant heart, liver, kidney or central nervous system disease Medical diagnosis placing the subject at high risk of surgical complications Current smoker History of prior malignancy except for cervical cancer in stage 1a or 1b after 3 years. HIV, mycobacteria, hepatitis B, or C. Present or recent systemic infection Chemical and/or alcohol dependency or abuse Presence of low lying pelvic kidney BMI greater than 30 kg/m ²	Number of successful live births after uterus transplant and IVF Full term birth by cesarian section after IVF followed by uterus transplant [TF: 2 years after transplantation]	Pregnancy complications: Hypertension Pre-eclampsia Intrauterine growth restriction Premature rupture of membranes Preterm delivery Intrauterine fetal demise Neonatal complications: birth defects perinatal infections low birth weight neonatal death neonatal intensive care unit admissions
NCT02656550	20 - 35 Years	Diabetes mellitus Type I and II known hypersensitivity to Tacrolimus, Thymoglobulin or CellCept Existing hypertension Previous oncology patients <5 years in remission Body Mass index >30 Active Infection Seropositivity for HIV, HBV, HCV, HTLV-I Any medical diagnosis placing the subject at high risk of surgical complications Non-smoker No Alcohol or drug abuse	Number of successful live births after uterine transplant and IVF. Full term birth by cesarean section. [TF: 2 years after transplant]	
NCT02409147	21 - 35 Years	Intact native ovaries No medical contraindication to transplantation No medical contraindication to reproduction and gestation in a transplanted uterus. Congenital or acquired uterine factor infertility (UFI) Counseled about alternate options for family building Previous oncology patients <5 years in remission	Successful Uterine Transplant Graft implantation and take (without rejection) successful menstruation for a set period.	

		<p>Negative evaluation for other relevant congenital abnormalities (such as a pelvic kidney).</p> <p>Neovaginal creation surgery prior to uterine transplant for women with Mullerian agenesis</p> <p>Intact ovaries and adequate ovarian reserve</p> <p>Good psychological evaluation</p> <p>Stable relationship</p> <p>No evidence of coercion;</p> <p>Financial capacity to cover anticipated expenses of assisted reproductive services.</p>	<p>IVF, pregnancy and delivery of the baby via C-section.</p> <p>[TF: 2 years];</p>	
NCT01844362	18 - 39 Years	<p>less than 39 years; good general health</p> <p>Exclusion Criteria: poor ovarian reserve or older than 39 years systemic or psychiatric disease</p>	<p>Surviving transplants (12 months) [TF: up to 3 years after transplantation]</p>	<p>Pregnancy rate [TF up to 3 years after transplantation]; Live birth rate [TF: up to 4 years after transplantation]</p>
NCT02637674	25 - 36 Years	<p>Women with AUFI couple living together for at least two years BMI \leq 30 kg/m²</p> <p>At least 12 months from colpoplasty surgery</p> <p>At least 12 months from diagnosis of uterine infertility</p> <p>Nulliparous</p> <p>Compliance with the legal criteria of medically assisted procreation</p> <p>Signed informed consent by the patient and spouse</p> <p>Prior psychological evaluation not contraindicating participation in the study</p> <p>Normal ovarian function and satisfactory ovarian reserve</p> <p>At least 10 embryos obtained by IVF</p> <p>No previous major abdomino-pelvic surgery</p> <p>No previous ileal or sigmoid colpoplasty</p> <p>History of cancer</p> <p>Active tobacco consumption</p> <p>Hypertension (HT),</p>	<p>Successful uterus transplant Success will be measured by by the occurrence of at least two spontaneous menstrual cycles during the first year following the UT. [TF: 12 month after each transplantation]</p>	<p>UT complications [TF: up to 41 after transplantation] Successful of pregnancies achieved [TF: up to 30 months after transplantation] Pregnancy complications after UT [TF: up to 39 months after transplantation] Successful of births achieved [TF: up to 39 months after transplantation.]</p>

	<p>Type 1 or 2 diabetes</p> <p>Chronic kidney disease</p> <p>Evolving cardiovascular pathology</p> <p>Psychiatric disease</p> <p>Contraindication to one of the treatments used in the study</p> <p>Rare blood group AB or B,</p> <p>Presence of anti-HLA antibodies</p> <p>Negative Epstein-Barr virus serology</p> <p>HIV or hepatitis C infection,</p> <p>Hepatitis B (acute, chronic, treated)</p> <p>Single kidney</p> <p>Detected cardiac pathology</p> <p>Dermatological, stomatological and/or ear, nose, and throat (ENT) pathology/ies contraindicating treatment with ISDs</p> <p>Thoracic-abdominal-pelvic CT scan anomalies contraindicating UT and the use of treatment with ISDs</p> <p>Increased risk of miscarriage (thrombophilia, abnormal karyotype)</p> <p>Separation of the couple.</p> <p>Spouse/partner with azoospermia</p> <p>Less than 10 frozen embryos obtained</p> <p>Separation of the couple.</p> <p>Previous uterine transplantation</p> <p>Donors:</p> <p>Brain dead female ≥ 18 years old and ≤ 50 years old.</p> <p>Length of no flow > 10 min</p> <p>Pregnancy at the time of brain death</p> <p>Time from delivery < 3 months</p> <p>Positive oncogen human papillomavirus (HPV) test (16 and 18)</p> <p>Myomas > 3 cm and/or endoluminal fibroid and/or endometrial polyps and/or heterogenous annexial cyst seen in a pelvic ultrasound or CT scan</p> <p>Multi-scarred uterus (≥ 2 uterine scars)</p>		
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		<p>Registered in the national registry of persons who refuse to donate any organ.</p> <p>Opposition to the uterine retrieval from the donor's relatives.</p> <p>Uterine agenesis and uterine malformation</p> <p>Criteria usually seen as contraindicating retrieval (HIV+, evolutive neoplasia, etc.)</p>		
NCT02741102	18 - 40 years	<p>Recipient:</p> <p>Woman with AUFI</p> <p>Able to produce at least 6 normal embryos</p> <p>Reasonable weight with BMI less than 30.</p> <p>Normal kidney function</p> <p>Able to undergo transplant and be compliant with treatment</p> <p>Stable partner and social supports</p> <p>Partner willing to undergo psychological evaluation and receive immunizations as recommended</p> <p>Stable home environment to support a child</p> <p>No smoking, alcohol use or use of illicit drugs</p> <p>No condition that would make pregnancy or taking anti rejection medicines too risky.</p> <p>No active infection: Human Immunodeficiency Virus (HIV) , Tuberculosis, Hepatitis B, Hepatitis C</p> <p>No history of extensive abdominal or pelvic surgery or abnormal Papanicolaou test (PAP smear) or genital warts</p> <p>History of pelvic inflammatory disease</p> <p>Donor.</p> <p>Age over 40 up to age 60</p> <p>Has completed having a family</p> <p>No previous miscarriages</p> <p>Able to take a birth control pill containing estrogen</p> <p>Weight reasonable with BMI (Body Mass Index) of 30 or less</p> <p>Good social supports</p> <p>No smoking, alcohol use or use of illicit drugs</p> <p>No Psychiatric illness</p>	<p>Number of successful live births following uterus transplant/embryo transfer èTF: 2 years after uterine transplant]</p> <p>Full term live birth by caesarian section after uterus transplant and IVF</p>	<p>Complications during pregnancy</p> <p>Pre-eclampsia, hypertension, pre-term delivery</p> <p>Complications following uterine donation</p> <p>Excessive bleeding , infection and bladder dysfunction</p> <p>Impact of uterine donation on donor quality of life</p> <p>serial SF 36 QOL survey by psychiatrist at pre-donation and at follow-up appointments</p> <p>Impact of uterine transplant on quality of life [Time Frame: Up to 5 years after uterine transplant]</p> <p>Measured by serial SF 36 QOL survey by psychiatrist pre-transplant and at follow-up appointments.." Cost comparison for uterine</p>

		<p>No cervical or endometrial polyps (growths) or tumors in the uterus muscle</p> <p>No history of more than 1 Caesarean section, abnormal PAP smear or genital warts</p> <p>Internal scarring from extensive abdominal or pelvic surgery</p> <p>Hypertension, Coronary artery disease, Chronic Obstructive Lung disease (emphysema) and Diabetes</p> <p>Active cancer or incompletely treated cancer</p> <p>Active infection including Human Immunodeficiency Disease (HIV), Tuberculosis, Hepatitis B or Hepatitis C</p> <p>Significant history of either blood clots or bleeding tendencies</p> <p>Evidence of coercion or exchange of money or goods for donating the organ</p>		<p>transplant vs. surrogacy vs adoption [Time Frame: Up to 5 years after uterine transplant]</p> <p>At the end of the study, investigators will calculate average cost of each modality, i.e. transplant vs surrogacy vs adoption to compare the three alternatives to infertility</p>
NCT02987023	20 - 38 Years	<p>Woman with AUFI</p> <p>BMI<30</p> <p>No systemic disease</p> <p>No psychiatric disease</p>	<p>Live births after uterus transplantation [TF: 5 years]</p> <p>Assessed by records from birthing unit and Swedish National Birth registry</p>	<p>Development of children after uterus transplantation [TF: 8 years]</p> <p>Assessed by growth parameters and neuropsychiatric tests (Bayley Mental Scale, M-CHAT, CBCL, WPPSI-IV)</p>
NCT03048396	20 - 40 Years	<p>Woman with AUFI</p> <p>BMI<30</p> <p>No systemic disease</p> <p>No psychiatric disease</p>		