

Ethics Committee approved studies

2012-099 局所進行性または転移性腎癌に対する術前分子標的薬治療効果の検討

Efficacy of presurgical targeting therapy on tumor shrinkage in patients with advanced renal cell carcinoma (UMIN000025209)

Patients: Advanced kidney cancer (cT3-4, N+ or oligo-metastasis)

Interventions: presurgical molecular-targeting therapy

Comparisons: historical cohorts, subgroup analysis

Outcomes: radiological response, pathological response, prognosis, and overall survival

Design: observational, retrospective or prospective, non-randomized

2012-228 泌尿器腫瘍の治療反応と進展予知を目的とした遺伝子解析研究

Gene analysis for prediction of therapeutic response and progress in urological cancers

Patients: Urologic diseases (Adrenal, kidney, ureter, bladder, prostate, seminal vesicle, urethra, penis, testis, Epididymis)

Interventions: standard treatment based on guideline, gene analysis (blood)

Comparisons: subgroup analysis

Outcomes: diagnosis marker, QOL, recurrence, prognosis, and overall survival

Design: observational, retrospective or prospective, non-randomized

2013-075 抗癌剤治療に伴う副作用と QOL・身体負担についての臨床研究

Clinical studies on the side effects and QOL associated with the anti-cancer drug treatment

Patients: Urologic diseases (Adrenal, kidney, ureter, bladder, prostate, seminal vesicle urethra, penis, testis, Epididymis)

Interventions: standard treatment based on guideline, systemic chemotherapy using anticancer agents

Comparisons: subgroup analysis

Outcomes: QOL, risk factors, recurrence, prognosis, and overall survival

Design: observational, retrospective or prospective, non-randomized

2013-076 蛍光標識グルコースを用いた泌尿器癌診断法の開発

Improvement of the sensitivity and specificity of urological cancer diagnostic method using a fluorescent labeled glucose

Patients: Urologic diseases (Adrenal, kidney, ureter, bladder, prostate, seminal vesicle urethra, penis, testis, Epididymis)

Interventions: standard treatment based on guideline, fluorescent labeled glucose analysis (tissue) in surgical materials

Comparisons: subgroup analysis

Outcomes: diagnosis marker, detection, recurrence, prognosis, and overall survival

Design: observational, retrospective or prospective, non-randomized

2013-103 腎移植・腎癌・透析患者の血管石灰化と心疾患・腎機能についての臨床研究

Clinical research on vascular calcification, cardiovascular disease and kidney function in patients with renal, transplantation, kidney cancer, and end-stage renal disease

Patients: kidney cancer, end-stage renal disease, kidney transplantation

Interventions: standard treatment based on guideline, aortic calcification analysis

Comparisons: subgroup analysis

Outcomes: cardiovascular disease, kidney function, prognosis, and overall survival

Design: observational, retrospective or prospective, non-randomized

2013-104 ABO 不適合腎移植患者の治療成績についての臨床研究

Clinical study of the ABO incompatible kidney transplant patients.

Patients: kidney transplantation

Interventions: standard treatment based on guideline

Comparisons: subgroup analysis (ABO compatible and incompatible)

Outcomes: risk factors, cardiovascular disease, kidney function, rejection, prognosis, and overall survival

Design: observational, retrospective or prospective, non-randomized

2013-105 腎静脈・下大静脈腫瘍血栓を伴う進行腎細胞癌の治療成績についての臨床研究

Clinical research on the treatment outcome of advanced renal cell carcinoma in patients with tumor thrombus in renal vein or inferior vena cava.

Patients: kidney cancer

Interventions: standard treatment based on guideline

Comparisons: subgroup analysis (localized vs. advanced)

Outcomes: risk factors, kidney function, prognosis, and overall survival

Design: observational, retrospective or prospective, non-randomized

2013-288 家族性に発症した腎骨形成の家系内調査と遺伝子解析に関する調査研究

Research on genetic analysis of familial renal bone formation

Patients: patient with familial renal bone formation

Interventions: nephrectomy

Comparisons: none

Outcomes: detection of genes of familial renal bone formation

Design: retrospective, non-randomized

201-314 高齢者透析患者の予後因子と予後についての臨床研究

Clinical studies of prognostic factors and prognosis of elderly dialysis patients

Patients: end-stage renal disease, dialysis

Interventions: standard therapy, based on guideline

Comparisons: subgroup analysis

Outcomes: risk factors, prognosis, and overall survival

Design: observational, retrospective or prospective, non-randomized

2013-315 抗凝固剤内服患者における前立腺生検の安全性についての臨床研究

The clinical study for the safety of prostate biopsy in patients with anticoagulants

Patients: prostate cancer suspected subjects

Interventions: prostate biopsy based on guideline

Comparisons: subgroup analysis (patients with anticoagulants and without anticoagulants)

Outcomes: difference in bleeding related adverse events, risk factors

Design: observational, retrospective or prospective, non-randomized

2014-002 前立腺癌におけるステロイドホルモンと治療効果に関する臨床研究

Clinical research on therapeutic effects of steroid hormones in patients with prostate cancer

Patients: prostate cancer

Interventions: standard treatment based on guideline, steroid hormone analysis in serum and prostate tissue

Comparisons: subgroup analysis

Outcomes: difference in steroid hormone levels among androgen deprivation therapy, prognostic marker,

recurrence, and overall survival

Design: observational, retrospective or prospective, non-randomized

2014-110 蛍光標識グルコースを用いた細胞診診断法の開発

Improvement of the sensitivity and specificity of urine cytology using a fluorescent labeled glucose

Patients: Urologic diseases (Adrenal, kidney, ureter, bladder, prostate, seminal vesicle, urethra, penis, testis, Epididymis)

Interventions: standard treatment based on guideline, fluorescent labeled glucose analysis (serum, sperm and

urine) in urine cytology

Comparisons: subgroup analysis

Outcomes: diagnosis marker, recurrence, prognosis, and overall survival

Design: observational, retrospective or prospective, non-randomized

2014-185 ファブリー病診療における Lyso-Gb3 の有用性の検討

The study for usefulness of Lyso-Gb3 in Fabry disease.

Patients: end-stage renal disease, dialysis

Interventions: Lyso-Gb3 analysis

Comparisons: subgroup analysis

Outcomes: diagnostic value of Lyso-Gb3, prognosis, and overall survival

Design: prospective or retrospective, non-randomized

2014-195 腎泌尿器疾患における糖鎖構造の変化に関する研究

The study on the glycan structure alternation in kidney and urological diseases

Patients: Urologic diseases (Adrenal, kidney, ureter, bladder, prostate, seminal vesicle, urethra, penis, testis, Epididymis)
Interventions: standard treatment based on guideline, glycan analysis (serum, sperm and urine)
Comparisons: subgroup analysis
Outcomes: diagnosis marker, QOL, recurrence, prognosis, and overall survival
Design: observational, retrospective or prospective, non-randomized

2014-196 慢性腎不全患者のエリスロポエチン低反応性と微量金属の関わりに関する臨床研究
Clinical studies for relationship between erythropoietin low reactivity and the involvement of trace metals in patients with chronic renal failure.

Patients: end-stage renal disease, dialysis
Interventions: trace metal analysis
Comparisons: subgroup analysis
Outcomes: erythropoietin low reactivity, anemia, event free survival, prognosis, and overall survival
Design: observational, retrospective or prospective, non-randomized

2015-047, 2015-258 尿路上皮癌に対する治療効果と術後の全身状態、再発、予後についての臨床研究

Retrospective study of post-therapeutic function and prognosis for urothelial carcinoma

Patients: urothelial cancers (bladder, urethra, renal pelvis and ureter)
Interventions: standard treatment based on guideline, chemotherapy, surgery, radiotherapy
Comparisons: subgroup analysis
Outcomes: QOL, recurrence, prognosis, and overall survival
Design: observational, retrospective or prospective, non-randomized

2015-292 : 高リスク転移性前立腺癌に対する早期ドセタキセル治療の効果

The prognostic efficacy for early administration of hormone naïve metastatic prostate cancer: A prospective multicenter study

Patients: hormone naïve metastatic prostate cancer
Interventions: androgen deprivation therapy with 6 course of docetaxel therapy
Comparisons: subgroup analysis, historical cohort
Outcomes: QOL, recurrence, prognosis, and overall survival
Design: observational, retrospective or prospective, non-randomized

2015-184, 2016-225 腎・泌尿器疾患に対する治療効果と治療後の状態・予後についての臨床研究

A study of post-therapeutic function and prognosis for urological disease

Patients: all urological disease (adrenal, kidney, ureter, bladder urethra, prostate, testis, penis, epididymis, renal failure, renal transplantation)
Interventions: standard treatment based on guideline
Comparisons: subgroup analysis, historical cohort
Outcomes: QOL, recurrence, prognosis, and overall survival

Design: observational, retrospective or prospective, non-randomized

2016-1082 泌尿器疾患を伴う高齢者におけるフレイル（虚弱性）評価とアウトカムについての臨床研究 **Prospective study of frailty in urological cancer for prognosis (UMIN000025057)**

Patients: all urological disease (adrenal, kidney, ureter, bladder urethra, prostate, testis, penis, renal failure, renal transplantation)

Interventions: frailty measurements using G8 screening, frail questionnaire, handgrip strength, gait speed, blood and serum test, standard treatment based on guideline

Comparisons: subgroup analysis, historical cohort

Outcomes: QOL, recurrence, prognosis, and overall survival

Design: observational, retrospective or prospective, non-randomized