

[Protocol No. AKR-002]

転移性腎癌に対する IIG 療法 (28-day cycle)

適応条件：IFN 抵抗性転移症例

| | | | |
|---------------|-----------------------|---------------|-------|
| Gemcitabine | 1000mg/m ² | days 1, 8, 15 | div. |
| IFN- α | 300 万単位 | 2 回/week | i. m. |
| IL-2 | 70 万単位 | 2 回/week | s. c. |

♪ 投与上限計 3 コースを目安に。治療開始 3, 6m 後に CT で効果判定。

参考文献：Neri B et al. J Urol 168, 956-958, 2002.

<原法：28-day cycle, phase II study for metastatic RCC>

| | | | |
|---------------|--------------------------|-----------------|-------|
| Gemcitabine | 1000mg/m ² | day1, 8, 15, 28 | div. |
| IFN- α | 3 × 10 ⁶ IU | 3 times/week | i. m. |
| IL-2 | 4.5 × 10 ⁵ IU | 5days/week 1, 2 | s. c. |

<効果> n=15, 奏効率 28%, NC rate 47%,

median survival 20 mos, median time to progression 14 mos.

<Grade 3-4 toxicity>好中球減少(7%), (flu-like symptom, fatigue)

参考文献：Ryan CW et al. Cancer 94, 2602-2609, 2002.

<原法：28-day cycle, phase II study for metastatic RCC>

| | | | |
|---------------|---------------------------|-------------|------------------|
| Gemcitabine | 600mg/m ² | day1, 8, 15 | div. |
| IFN- α | 10 × 10 ⁶ IU | 2times/week | i. m. |
| IL-2 | 11 × 10 ⁶ IU | 4days/week | s. c. |
| 5-FU | 200mg/m ² /day | day1-21 | continuous i. v. |

<効果> n=41, 奏効率 14.6%, CR 2.4%, PR 12.2%, NC rate 56%,

median survival 20.6 mos, median time to progression 6.6 mos.

<Grade 3-4 toxicity> 発熱28%, 食欲不振13%, 嘔気8%, 好中球減少(28%),
胃炎18%、貧血3%