・局PD　(Progressive Disease)　　最大径及びそれに直角に交わる最大径の積が25%以上増大したもの

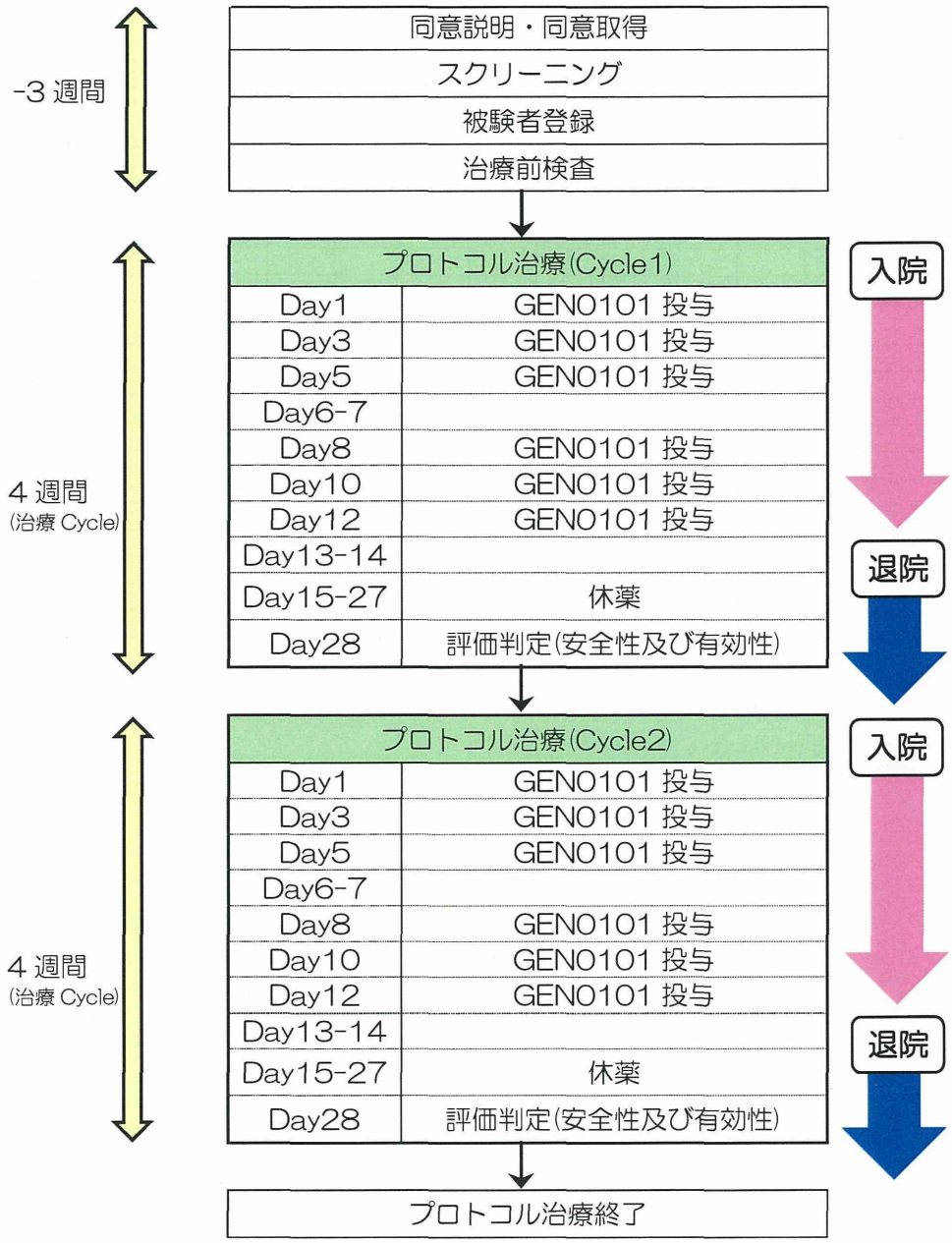
2.　腫瘍免疫誘導能の確認

以下の項目について、各用量群で記述統計量を算出する。

(1)　NK 細胞活性（外注検査）（全血）

(2)　IL-6（外注検査）（血清）

(3)　IFN-γ（外注検査）（全血）


-3 週間
同意説明・同意取得
スクリーニング
被験者登録
治療前検査
4 週間
(治療 Cycle)
プロトコル治療(Cycle1)
Day1 GEN0101 投与
Day3 GEN0101 投与
Day5 GEN0101 投与
Day6-7
Day8 GEN0101 投与
Day10 GEN0101 投与
Day12 GEN0101 投与
Day13-14
Day15-27 休薬
Day28 評価判定(安全性及び有効性)
入院
退院
4 週間
(治療 Cycle)
プロトコル治療(Cycle2)
Day1 GEN0101 投与
Day3 GEN0101 投与
Day5 GEN0101 投与
Day6-7
Day8 GEN0101 投与
Day10 GEN0101 投与
Day12 GEN0101 投与
Day13-14
Day15-27 休薬
Day28 評価判定(安全性及び有効性)
入院
退院
プロトコル治療終了

治験のスケジュール

期間	スクリーニング	投与前検査[2]	Cycle1					Cycle2					手術時中止時
時期(Day)	-21~0	~0	1,3,5	6~7	8,10,12	13~14	28	1,3,5	6~7	8,10,12	13~14	28	
同意取得	x												
被験者登録	x												
プリックテスト	x												
治験薬投与			x		x			x		x			
被験者背景	x												
診察・問診	x		◀·····	·····	·····	·····▶	x	◀·····	·····	·····	·····▶	x	x
バイタルサイン	x		x[1]		x[1]			x[1]		x[1]		x	x
身長・体重	x												
臨床病期	x											x	x
Performance Status	x											x	x
血液学的検査・血液生化学的検査	x			x		x	x		x		x	x	x
尿検査	x					x	x				x	x	x
腫瘍マーカー		x					x					x	x
血中抗HVJ-E抗体		x					x					x	x
HIV1,2,HBV,HCV検査	x												x[3]
妊娠検査(β-HCG)[4]	x												
心電図[5]	x		◀·····	·····	·····	·····	·····	·····	·····	·····	·····	·····	·····▶
胸部X線検査	x											x	x
腫瘍評価[6]		x					x					x	x
免疫モニタリング		x				x					x	x	x
有害事象	x		◀·····	·····	·····	·····	·····	·····	·····	·····	·····	·····	·····▶
治療歴/薬剤投与歴/併用薬	x		◀·····	·····	·····	·····	·····	·····	·····	·····	·····	·····	·····▶

1) 治験薬投与前後に実施する。
2) 投与前検査は被験者登録後、治験薬投与前日までに実施する。
3) HBV(HBe抗原)及びHCV(HCVmRNA)検査のみ実施する。
4) 女性のみ実施する。
5) 治験期間中は、医学的に必要と判断された場合のみに実施する。
6) 治験期間を通じて、同一の測定方法を用いる。

Ⅱ．研究成果の刊行に関する一覧表

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