

総括報告書

作成日:2025年1月31日

JCOG1611:「遠隔転移を有するまたは再発膵癌に対するゲムシタビン+ナブパクリタキセル併用療法/modified FOLFIRINOX 療法/S-IROX 療法の第Ⅱ/Ⅲ 相比較試験」

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1 臨床研究の名称等

実施計画の実施計画番号	JRCTs031190009
研究名称	JCOG1611:遠隔転移を有するまたは再発膵癌に対するゲムシタビン+ナブパクリタキセル併用療法/modified FOLFIRINOX療法/S-IROX療法の第Ⅱ/Ⅲ相比較試験
平易な研究名称	JCOG1611:転移または再発の膵がんに対する化学療法の臨床試験
認定臨床研究審査委員会の名称(認定番号)	国立研究開発法人国立がん研究センター中央病院臨床研究審査委員会(CRB3180008)

試験概要	目的 遠隔転移を有するまたは再発膵癌患者を対象に、標準治療であるゲムシタビン+ナブパクリタキセル併用療法(GnP療法)に対する、modified FOLFIRINOX療法(mFOLFIRINOX療法)と、S-1+イリノテカン+オキサリプラチン併用療法(S-IROX療法)の優越性をランダム化第Ⅱ/Ⅲ相試験において検証する。 対象 組織診または細胞診で腺癌または腺扁平上皮癌と診断された、遠隔転移を有するまたは再発膵癌。年齢 20 歳以上 75 歳以下。PS 0-1。 治療 A 群:GnP 療法(ナブパクリタキセル 125 mg/m² day 1、8、15、ゲムシタビン 1,000 mg/m² day 1、8、15、4 週ごと)、B 群:mFOLFIRINOX 療法(オキサリプラチン 85 mg/m² day 1、ロイコボリン 200 mg/m² day 1、イリノテカン 150 mg/m² day 1、5-FU 持続静注 2,400 mg/m² day 1-3、2 週ごと)、C 群:S-IROX 療法(オキサリプラチン 85 mg/m² day 1、イリノテカン 150 mg/m² day 1、S-1 80-120 mg/day day 1-7、2 週ごと)をプロトコル治療中止規準に該当するまで継続する。 エンドポイント(第Ⅲ相部分) Primary endpoint:全生存期間 Secondary endpoints:無増悪生存期間、奏効割合、有害事象発生割合、重篤な有害事象発生割合、各薬剤の dose intensity 登録数・研究期間 予定登録数:732 人、予定登録期間:5 年、追跡期間:登録終了後 1 年
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2 臨床研究結果の要約

観察期間終了日	2024年5月14日				
Completion date	May 14, 2024				
実施症例数	527人				
Result actual enrolment	527 patients				
臨床研究の対象者の背景情報	年齢中央値は 65 歳(35-75 歳)、PS 0 が 355 人、PS 1 が 172 人、男性 303 人、女性 224 人であった。遠隔転移を有する患者は 499 人、再発患者は 28 人であった。				
Baseline Characteristics		A群 (GnP療法) N=176	B群 (mFOLFIRINOX 療法)N=175	C群 (S-IROX療法) N=176	合計 N=527
	Age				
	Median	65	67	65	65
	Range	38-75	45-75	35-75	35-75
	PS				
	0	118	118	119	355
	1	58	57	57	172
	Sex				
	Male	87	104	112	303
	Female	89	71	64	224
	Disease status				
	Metastatic	165	167	167	499
	Recurrent	11	8	9	28
臨床研究のデザインに応じた進行状況に関する情報	登録ペースは、当初予測したペースを若干下回るもののほぼ予想通りであった。登録期間中に、第Ⅱ相部分の解析のため、および、ナブパクリタキセル供給停止の影響のため、の2回の登録一時停止期間があった。 施設毎の患者登録数は、国立がん研究センター中央病院が64人、神奈川県立がんセンターが52人、金沢大学医学部が42例と上位3施設で約30%を占めていた。 プロトコル治療中止理由の多くはプロトコル治療無効(261人)であった。有害事象による中止は153人であった。中間解析結果に基づく試験早期中止による中止は90人であった。				
Participant flow	527 patients randomly assigned 176 assigned to nab-paclitaxel plus gemcitabine 141 included in the planned interim analysis 176 eligible 2 did not receive treatment 174 received treatment 174 discontinued treatment 92 progressive disease 42 adverse event 1 died 2 withdrew 33 due to early trial termination 4 other 176 included in the intention-to-treat population 174 included in the safety population 175 assigned to modified FOLFIRINOX 143 included in the planned interim analysis 1 ineligible 1 diagnosed with NSCLC 174 eligible 3 did not receive treatment 171 received treatment 171 discontinued treatment 85 progressive disease 59 adverse event 1 withdrew 25 due to early trial termination 1 other 175 included in the intention-to-treat population 171 included in the safety population 176 assigned to S-IROX 142 included in the planned interim analysis 1 ineligible 1 homozygous UGT1A1 175 eligible 1 did not receive treatment 174 received treatment 174 discontinued treatment 84 progressive disease 52 adverse event 2 died 1 withdrew 32 due to early trial termination 3 other 176 included in the intention-to-treat population 174 included in the safety population				
疾病等の発生状況のまとめ	治療関連死亡(TRD)はS-IROX療法群の1人に生じた。事象名は脳卒中であり、化学療法に伴う食欲不振や倦怠感の関与が否定できないものと判断された。Grade 3または4の消化器毒性はmFOLFIRINOX療法群とS-IROX療法群でGnP療法群よりも高頻度であった。				

	観察期間中の主な有害事象は以下のとおりである。																																																																																																																																																						
	<table><tr><th></th><th colspan="3">Nab-paclitaxel + gemcitabine (n=174)</th><th colspan="3">mFOLFIRINOX (n=171)</th><th colspan="3">S-IROX (n=174)</th></tr><tr><th></th><th>Grade 1-2</th><th>Grade 3</th><th>Grade 4</th><th>Grade 1-2</th><th>Grade 3</th><th>Grade 4</th><th>Grade 1-2</th><th>Grade 3</th><th>Grade 4</th></tr><tr><td>好中球減少</td><td>51 (29.3%)</td><td>79 (45.4%)</td><td>26 (14.9%)</td><td>65 (38.0%)</td><td>49 (28.7%)</td><td>39 (22.8%)</td><td>79 (45.4%)</td><td>37 (21.3%)</td><td>30 (17.2%)</td></tr><tr><td>白血球減少</td><td>55 (31.6%)</td><td>52 (29.9%)</td><td>8 (4.6%)</td><td>68 (39.8%)</td><td>29 (17.0%)</td><td>9 (5.3%)</td><td>48 (27.6%)</td><td>21 (12.1%)</td><td>7 (4.0%)</td></tr><tr><td>貧血</td><td>118 (67.8%)</td><td>15 (8.6%)</td><td>4 (2.3%)</td><td>112 (65.5%)</td><td>13 (7.6%)</td><td>5 (2.9%)</td><td>101 (58.0%)</td><td>17 (9.8%)</td><td>2 (1.1%)</td></tr><tr><td>血小板減少</td><td>149 (85.6%)</td><td>6 (3.4%)</td><td>2 (1.1%)</td><td>141 (82.5%)</td><td>7 (4.1%)</td><td>1 (0.6%)</td><td>135 (77.6%)</td><td>13 (7.5%)</td><td>2 (1.1%)</td></tr><tr><td>発熱性好中球減少症</td><td>NA</td><td>6 (3.4%)</td><td>0</td><td>NA</td><td>15 (8.8%)</td><td>0</td><td>NA</td><td>13 (7.5%)</td><td>0</td></tr><tr><td>ニューロパシー</td><td>90 (51.7%)</td><td>19 (10.9%)</td><td>0</td><td>76 (44.4%)</td><td>14 (8.2%)</td><td>0</td><td>88 (50.6%)</td><td>13 (7.5%)</td><td>0</td></tr><tr><td>感染</td><td>3 (1.7%)</td><td>19 (10.9%)</td><td>0</td><td>6 (3.5%)</td><td>28 (16.4%)</td><td>0</td><td>5 (2.9%)</td><td>14 (8.0%)</td><td>1 (0.6%)</td></tr><tr><td>ALT 増加</td><td>117 (67.2%)</td><td>18 (10.3%)</td><td>1 (0.6%)</td><td>116 (67.8%)</td><td>18 (10.5%)</td><td>2 (1.2%)</td><td>119 (68.4%)</td><td>20 (11.5%)</td><td>0</td></tr><tr><td>AST 増加</td><td>113 (64.9%)</td><td>13 (7.5%)</td><td>1 (0.6%)</td><td>122 (71.3%)</td><td>15 (8.8%)</td><td>1 (0.6%)</td><td>136 (78.2%)</td><td>11 (6.3%)</td><td>1 (0.6%)</td></tr><tr><td>食欲不振</td><td>76 (43.7%)</td><td>9 (5.2%)</td><td>0</td><td>86 (50.3%)</td><td>39 (22.8%)</td><td>0</td><td>81 (46.6%)</td><td>48 (27.6%)</td><td>0</td></tr><tr><td>疲労</td><td>86 (49.4%)</td><td>5 (2.9%)</td><td>NA</td><td>74 (43.3%)</td><td>7 (4.1%)</td><td>NA</td><td>79 (45.4%)</td><td>11 (6.3%)</td><td>NA</td></tr><tr><td>悪心</td><td>49 (28.2%)</td><td>4 (2.3%)</td><td>NA</td><td>76 (44.4%)</td><td>15 (8.8%)</td><td>NA</td><td>82 (47.1%)</td><td>18 (10.3%)</td><td>NA</td></tr><tr><td>下痢</td><td>41 (23.6%)</td><td>2 (1.1%)</td><td>0</td><td>74 (43.3%)</td><td>14 (8.2%)</td><td>1 (0.6%)</td><td>67 (38.5%)</td><td>40 (23.0%)</td><td>0</td></tr></table>		Nab-paclitaxel + gemcitabine (n=174)			mFOLFIRINOX (n=171)			S-IROX (n=174)				Grade 1-2	Grade 3	Grade 4	Grade 1-2	Grade 3	Grade 4	Grade 1-2	Grade 3	Grade 4	好中球減少	51 (29.3%)	79 (45.4%)	26 (14.9%)	65 (38.0%)	49 (28.7%)	39 (22.8%)	79 (45.4%)	37 (21.3%)	30 (17.2%)	白血球減少	55 (31.6%)	52 (29.9%)	8 (4.6%)	68 (39.8%)	29 (17.0%)	9 (5.3%)	48 (27.6%)	21 (12.1%)	7 (4.0%)	貧血	118 (67.8%)	15 (8.6%)	4 (2.3%)	112 (65.5%)	13 (7.6%)	5 (2.9%)	101 (58.0%)	17 (9.8%)	2 (1.1%)	血小板減少	149 (85.6%)	6 (3.4%)	2 (1.1%)	141 (82.5%)	7 (4.1%)	1 (0.6%)	135 (77.6%)	13 (7.5%)	2 (1.1%)	発熱性好中球減少症	NA	6 (3.4%)	0	NA	15 (8.8%)	0	NA	13 (7.5%)	0	ニューロパシー	90 (51.7%)	19 (10.9%)	0	76 (44.4%)	14 (8.2%)	0	88 (50.6%)	13 (7.5%)	0	感染	3 (1.7%)	19 (10.9%)	0	6 (3.5%)	28 (16.4%)	0	5 (2.9%)	14 (8.0%)	1 (0.6%)	ALT 増加	117 (67.2%)	18 (10.3%)	1 (0.6%)	116 (67.8%)	18 (10.5%)	2 (1.2%)	119 (68.4%)	20 (11.5%)	0	AST 増加	113 (64.9%)	13 (7.5%)	1 (0.6%)	122 (71.3%)	15 (8.8%)	1 (0.6%)	136 (78.2%)	11 (6.3%)	1 (0.6%)	食欲不振	76 (43.7%)	9 (5.2%)	0	86 (50.3%)	39 (22.8%)	0	81 (46.6%)	48 (27.6%)	0	疲労	86 (49.4%)	5 (2.9%)	NA	74 (43.3%)	7 (4.1%)	NA	79 (45.4%)	11 (6.3%)	NA	悪心	49 (28.2%)	4 (2.3%)	NA	76 (44.4%)	15 (8.8%)	NA	82 (47.1%)	18 (10.3%)	NA	下痢	41 (23.6%)	2 (1.1%)	0	74 (43.3%)	14 (8.2%)	1 (0.6%)	67 (38.5%)	40 (23.0%)	0
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Adverse events	<table><tr><th></th><th colspan="3">Nab-paclitaxel + gemcitabine (n=174)</th><th colspan="3">mFOLFIRINOX (n=171)</th><th colspan="3">S-IROX (n=174)</th></tr><tr><th></th><th>Grade 1-2</th><th>Grade 3</th><th>Grade 4</th><th>Grade 1-2</th><th>Grade 3</th><th>Grade 4</th><th>Grade 1-2</th><th>Grade 3</th><th>Grade 4</th></tr><tr><td>Neutropenia</td><td>51 (29.3%)</td><td>79 (45.4%)</td><td>26 (14.9%)</td><td>65 (38.0%)</td><td>49 (28.7%)</td><td>39 (22.8%)</td><td>79 (45.4%)</td><td>37 (21.3%)</td><td>30 (17.2%)</td></tr><tr><td>White blood cell decreased</td><td>55 (31.6%)</td><td>52 (29.9%)</td><td>8 (4.6%)</td><td>68 (39.8%)</td><td>29 (17.0%)</td><td>9 (5.3%)</td><td>48 (27.6%)</td><td>21 (12.1%)</td><td>7 (4.0%)</td></tr><tr><td>Anemia</td><td>118 (67.8%)</td><td>15 (8.6%)</td><td>4 (2.3%)</td><td>112 (65.5%)</td><td>13 (7.6%)</td><td>5 (2.9%)</td><td>101 (58.0%)</td><td>17 (9.8%)</td><td>2 (1.1%)</td></tr><tr><td>Thrombocytopenia</td><td>149 (85.6%)</td><td>6 (3.4%)</td><td>2 (1.1%)</td><td>141 (82.5%)</td><td>7 (4.1%)</td><td>1 (0.6%)</td><td>135 (77.6%)</td><td>13 (7.5%)</td><td>2 (1.1%)</td></tr><tr><td>Fibrinocutopenia</td><td>NA</td><td>6 (3.4%)</td><td>0</td><td>NA</td><td>15 (8.8%)</td><td>0</td><td>NA</td><td>13 (7.5%)</td><td>0</td></tr><tr><td>Neuropathy</td><td>90 (51.7%)</td><td>19 (10.9%)</td><td>0</td><td>76 (44.4%)</td><td>14 (8.2%)</td><td>0</td><td>88 (50.6%)</td><td>13 (7.5%)</td><td>0</td></tr><tr><td>Infection</td><td>3 (1.7%)</td><td>19 (10.9%)</td><td>0</td><td>6 (3.5%)</td><td>28 (16.4%)</td><td>0</td><td>5 (2.9%)</td><td>14 (8.0%)</td><td>1 (0.6%)</td></tr><tr><td>ALT increased</td><td>117 (67.2%)</td><td>18 (10.3%)</td><td>1 (0.6%)</td><td>116 (67.8%)</td><td>18 (10.5%)</td><td>2 (1.2%)</td><td>119 (68.4%)</td><td>20 (11.5%)</td><td>0</td></tr><tr><td>AST increased</td><td>113 (64.9%)</td><td>13 (7.5%)</td><td>1 (0.6%)</td><td>122 (71.3%)</td><td>15 (8.8%)</td><td>1 (0.6%)</td><td>136 (78.2%)</td><td>11 (6.3%)</td><td>1 (0.6%)</td></tr><tr><td>Anorexia</td><td>76 (43.7%)</td><td>9 (5.2%)</td><td>0</td><td>86 (50.3%)</td><td>39 (22.8%)</td><td>0</td><td>81 (46.6%)</td><td>48 (27.6%)</td><td>0</td></tr><tr><td>Fatigue</td><td>86 (49.4%)</td><td>5 (2.9%)</td><td>NA</td><td>74 (43.3%)</td><td>7 (4.1%)</td><td>NA</td><td>79 (45.4%)</td><td>11 (6.3%)</td><td>NA</td></tr><tr><td>Nausea</td><td>49 (28.2%)</td><td>4 (2.3%)</td><td>NA</td><td>76 (44.4%)</td><td>15 (8.8%)</td><td>NA</td><td>82 (47.1%)</td><td>18 (10.3%)</td><td>NA</td></tr><tr><td>Diarrhea</td><td>41 (23.6%)</td><td>2 (1.1%)</td><td>0</td><td>74 (43.3%)</td><td>14 (8.2%)</td><td>1 (0.6%)</td><td>67 (38.5%)</td><td>40 (23.0%)</td><td>0</td></tr></table>		Nab-paclitaxel + gemcitabine (n=174)			mFOLFIRINOX (n=171)			S-IROX (n=174)				Grade 1-2	Grade 3	Grade 4	Grade 1-2	Grade 3	Grade 4	Grade 1-2	Grade 3	Grade 4	Neutropenia	51 (29.3%)	79 (45.4%)	26 (14.9%)	65 (38.0%)	49 (28.7%)	39 (22.8%)	79 (45.4%)	37 (21.3%)	30 (17.2%)	White blood cell decreased	55 (31.6%)	52 (29.9%)	8 (4.6%)	68 (39.8%)	29 (17.0%)	9 (5.3%)	48 (27.6%)	21 (12.1%)	7 (4.0%)	Anemia	118 (67.8%)	15 (8.6%)	4 (2.3%)	112 (65.5%)	13 (7.6%)	5 (2.9%)	101 (58.0%)	17 (9.8%)	2 (1.1%)	Thrombocytopenia	149 (85.6%)	6 (3.4%)	2 (1.1%)	141 (82.5%)	7 (4.1%)	1 (0.6%)	135 (77.6%)	13 (7.5%)	2 (1.1%)	Fibrinocutopenia	NA	6 (3.4%)	0	NA	15 (8.8%)	0	NA	13 (7.5%)	0	Neuropathy	90 (51.7%)	19 (10.9%)	0	76 (44.4%)	14 (8.2%)	0	88 (50.6%)	13 (7.5%)	0	Infection	3 (1.7%)	19 (10.9%)	0	6 (3.5%)	28 (16.4%)	0	5 (2.9%)	14 (8.0%)	1 (0.6%)	ALT increased	117 (67.2%)	18 (10.3%)	1 (0.6%)	116 (67.8%)	18 (10.5%)	2 (1.2%)	119 (68.4%)	20 (11.5%)	0	AST increased	113 (64.9%)	13 (7.5%)	1 (0.6%)	122 (71.3%)	15 (8.8%)	1 (0.6%)	136 (78.2%)	11 (6.3%)	1 (0.6%)	Anorexia	76 (43.7%)	9 (5.2%)	0	86 (50.3%)	39 (22.8%)	0	81 (46.6%)	48 (27.6%)	0	Fatigue	86 (49.4%)	5 (2.9%)	NA	74 (43.3%)	7 (4.1%)	NA	79 (45.4%)	11 (6.3%)	NA	Nausea	49 (28.2%)	4 (2.3%)	NA	76 (44.4%)	15 (8.8%)	NA	82 (47.1%)	18 (10.3%)	NA	Diarrhea	41 (23.6%)	2 (1.1%)	0	74 (43.3%)	14 (8.2%)	1 (0.6%)	67 (38.5%)	40 (23.0%)	0
	Nab-paclitaxel + gemcitabine (n=174)			mFOLFIRINOX (n=171)			S-IROX (n=174)																																																																																																																																																
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主要評価項目及び副次評価項目のデータ解析及び結果	本試験では、有効性のprimary endpointとして全生存期間を設定し、試験期間中に1回の中間解析が予定された。2023年3月11日に行われた中間解析時点で、527人の患者が登録され、426人のデータが中間解析に用いられた。全生存期間はGnP療法群17.1か月に対し、mFOLFIRINOX療法群では14.0か月 (HR 1.31, 95% CI 0.97–1.77)、S-IROX療法群では13.6か月 (HR 1.35, 95% CI 1.00–1.82)であった。試験を継続した場合に最終解析時点において優越性を示す予測確率は、mFOLFIRINOX療法群が0.73%、S-IROX療法群が0.48%であった。このため、本試験は無効中止となった。2024年3月に行われた最終追跡時には、527人の患者を対象に解析された。全生存期間はGnP療法群15.3か月に対し、mFOLFIRINOX療法群では12.5か月 (HR 1.27, 95% CI 1.01–1.61)、S-IROX療法群では13.2か月 (HR 1.23, 95% CI 0.98–1.56)であった。																																																																																																																																																						

Outcome measures	The primary endpoint for the efficacy of this study was overall survival, and one interim analysis was planned during the study period. At the time of the interim analysis, a total of 527 patients were enrolled and 426 patients were included in the interim analysis. The median overall survival was 14.0 months (HR 1.31, 95% CI 0.97–1.77) and 13.6 months (HR 1.35, 95% CI 1.00–1.82) in the mFOLFIRINOX and S-IROX arms, respectively, as compared with 17.1 months in the nab-paclitaxel + gemcitabine arm. The predictive probability of achieving superiority in the final analysis was 0.73% and 0.48% in the mFOLFIRINOX and S-IROX arms, respectively. Thus, this study was terminated owing to its futility. The median OS was 15.3 months in the GnP arm, 12.5 months in the mFOLFIRINOX arm (HR 1.27, 95% CI 1.01–1.61), and 13.2 months in the S-IROX arm (HR 1.23, 95% CI 0.98–1.56).
簡潔な要約	遠隔転移を有するまたは再発膵癌の一次治療としては、GnP療法が、mFOLFIRINOX療法やS-IROX療法と比較して推奨される。
Brief summary	Compared to mFOLFIRINOX or S-IROX, nab-paclitaxel + gemcitabine is recommended as the first-line treatment for metastatic or recurrent pancreatic cancer.
公開予定日	2025年4月10日
結果に関する最初の出版物での発表日	
Date of the first journal publication of results	
結果と出版物に関するURL (複数可)	
URL hyperlink(s) related to results and publications	

3 IPD (individual clinical trial participant-level data) シェアリング (匿名化された臨床研究の対象者単位データの共有)

IPDデータを共有する計画	☐ あり ☒ なし ☐ 未定
Plan to share IPD	None
計画の説明	非該当
Plan description	NA