CONTROLLO DI MALATTIA NEI NEUROBLASTOMA (NB) REFRATTARI E RECIDIVATI (RR): UNA QUESTIONE APERTA

FAD SINCRONA 10 Luglio 2026

Real World Evidence Chemioimmunoterapia

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Disclosures BARTOLOMEO ROSSI

Company name	Research support	Employee	Consultant	Stockholder	Speakers bureau	Advisory board	Other

Chemo-immunotherapy with dinutuximab beta in patients with relapsed/progressive high-risk neuroblastoma: does chemotherapy backbone matter?

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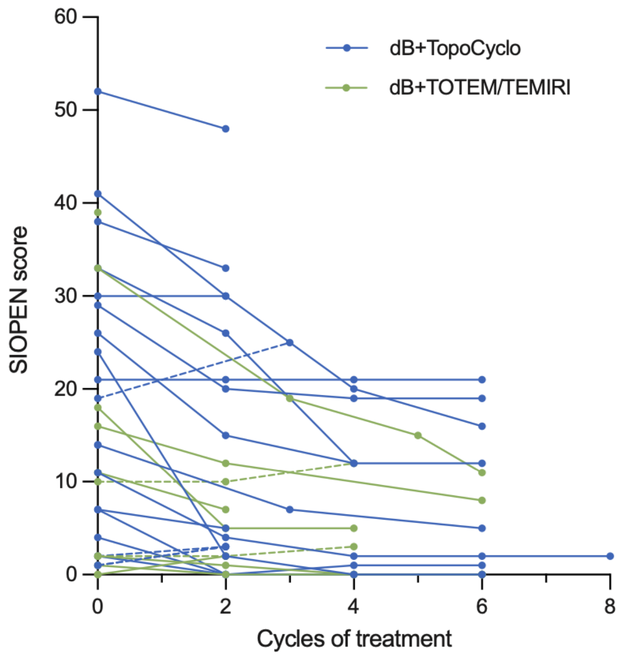
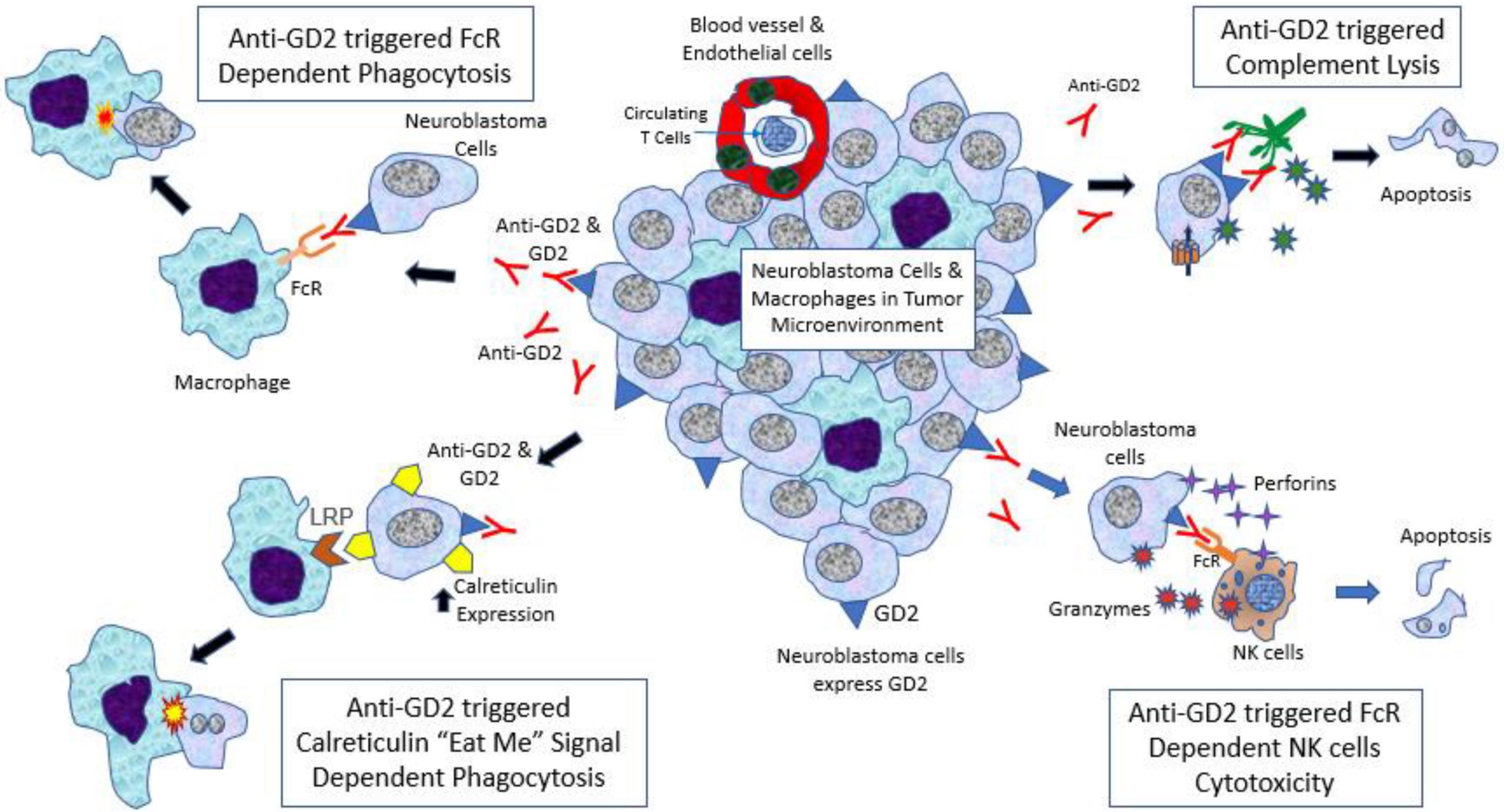


Best tumor response, n (%)	Overall ($n = 39$)	dB+TopoCyclo ($n = 24$)	dB+TOTEM/TEMIRI ($n = 15$)
CR	4 (10)	2 (8)	2 (13)
PR	10 (26)	6 (25)	4 (27)
MR	2 (5)	2 (8)	0 (0)
SD	8 (21)	4 (17)	4 (27)
PD	15 (38)	10 (42)	5 (33)

39 pazienti in off-label/compassionate use; ORR simile con TopoCyclo 42% e TOTEM/TEMIRI 40%.

Raiser et al., European Journal of Cancer, 2024

Meccanismo d'azione



Tre anticorpi anti-GD2 approvati: stato dell'arte nel neuroblastoma

1 INDICATIONS AND USAGE

Unituxin (dinutuximab) is indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy *[see Clinical Studies (14)]*.

DINUTUXIMAB

DINUTUXIMAB BETA

4.1 Therapeutic indications

Qarziba is indicated for the treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma, with or without residual disease. Prior to the treatment of relapsed neuroblastoma, any actively progressing disease should be stabilised by other suitable measures.

In patients with a history of relapsed/refractory disease and in patients who have not achieved a complete response after first line therapy, Qarziba should be combined with interleukin-2 (IL-2).

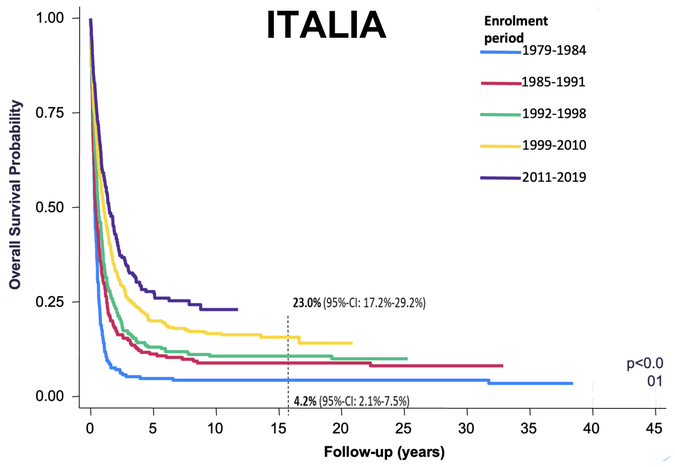
NAXITAMAB

1 INDICATIONS AND USAGE

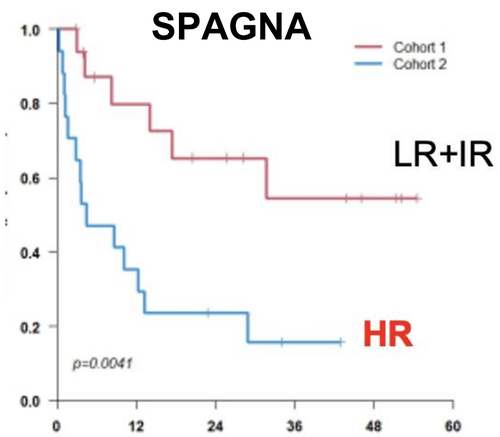
DANYELZA is indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.

This indication is approved under accelerated approval based on overall response rate and duration of response *[see Clinical Studies (14)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

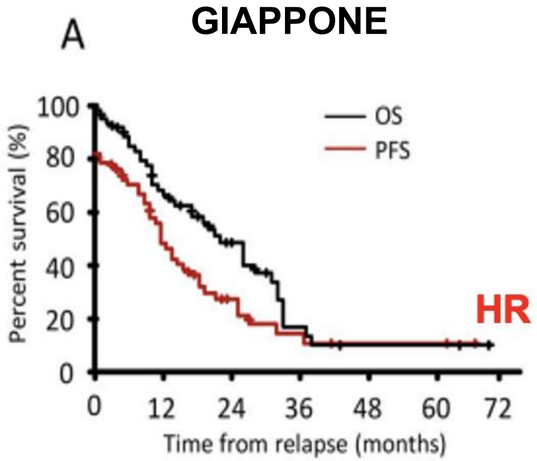
Sopravvivenza nel neuroblastoma R/R: un bisogno clinico ancora insoddisfatto



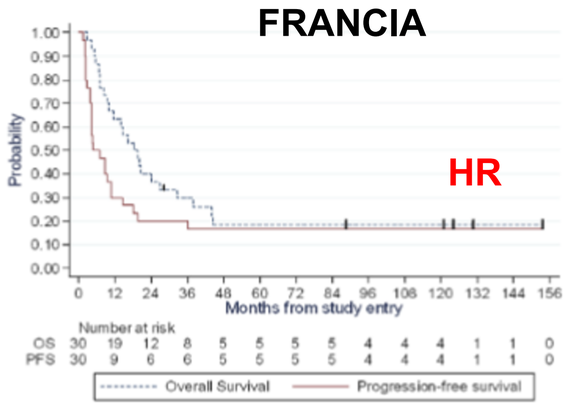
RINB



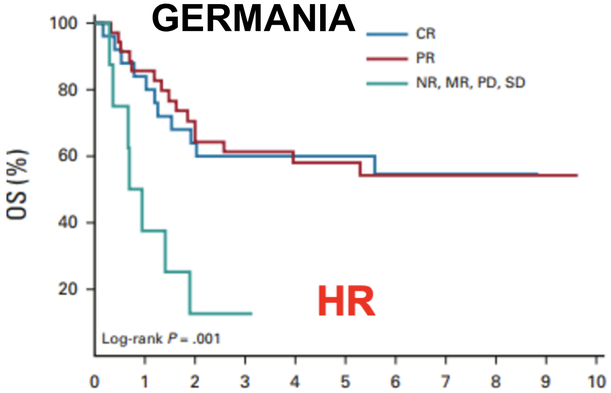
Munoz 2023



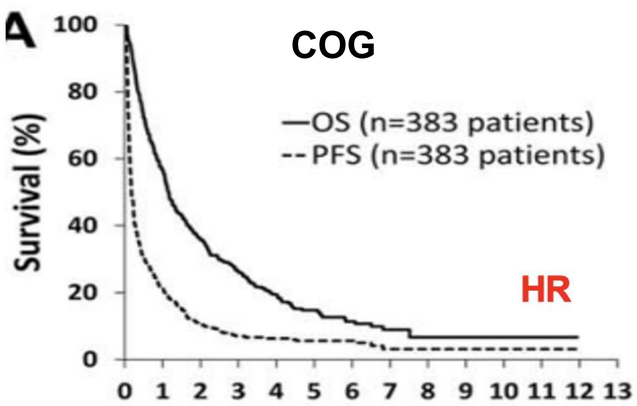
Hara 2022



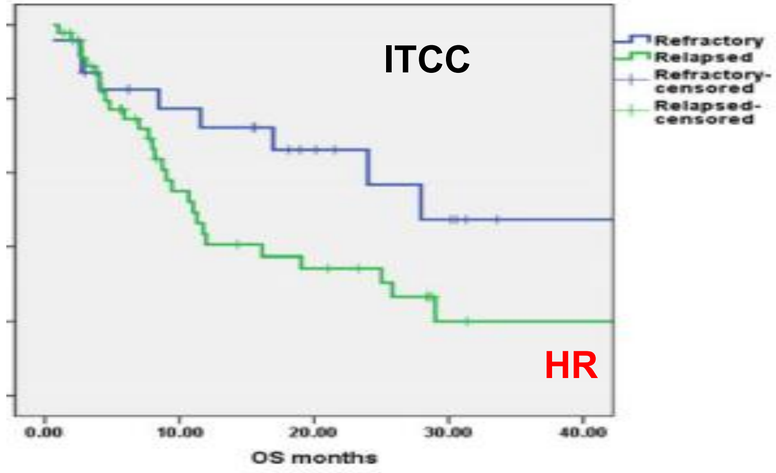
Servin 2023



Lang 2022



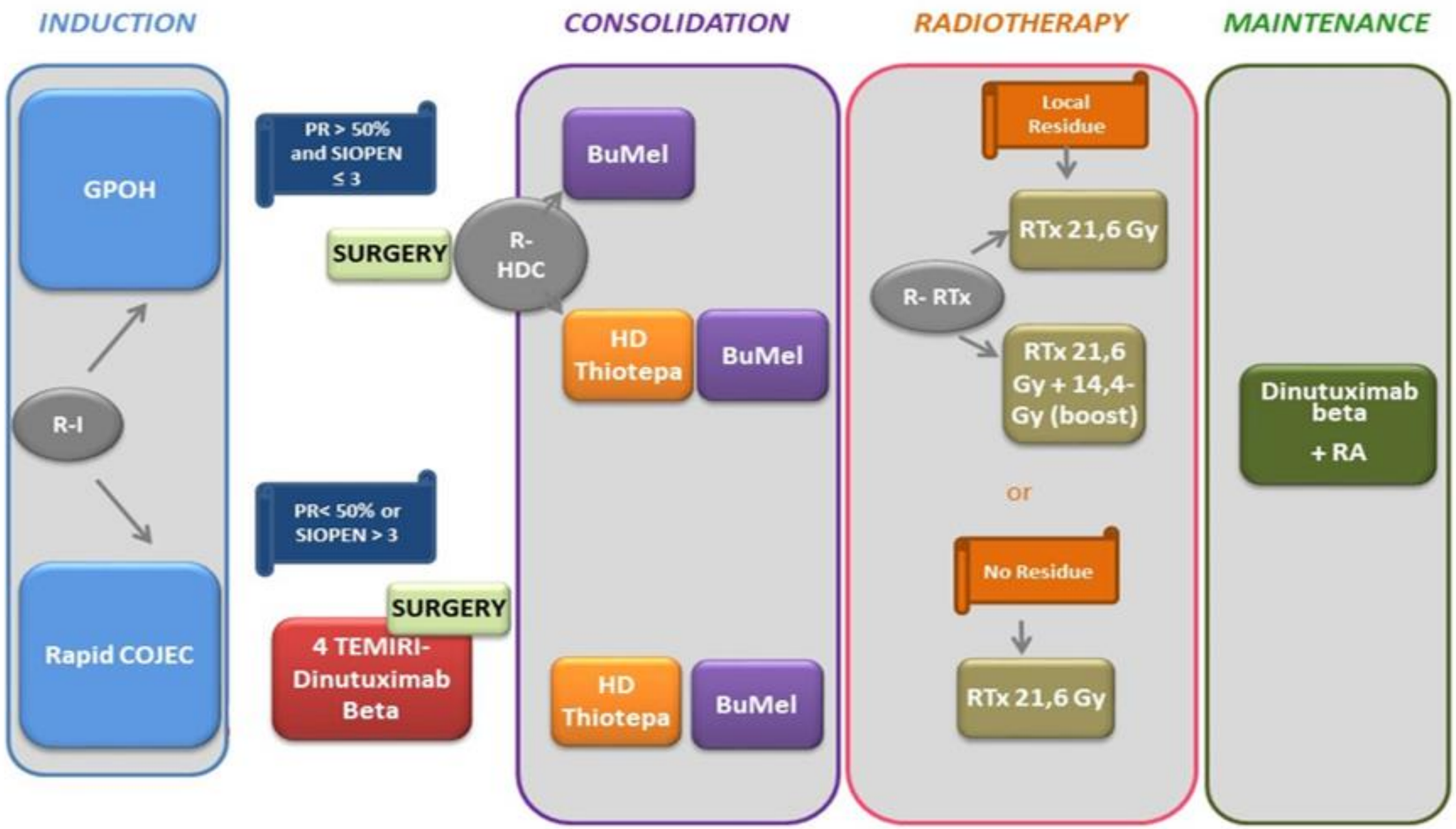
London 2018



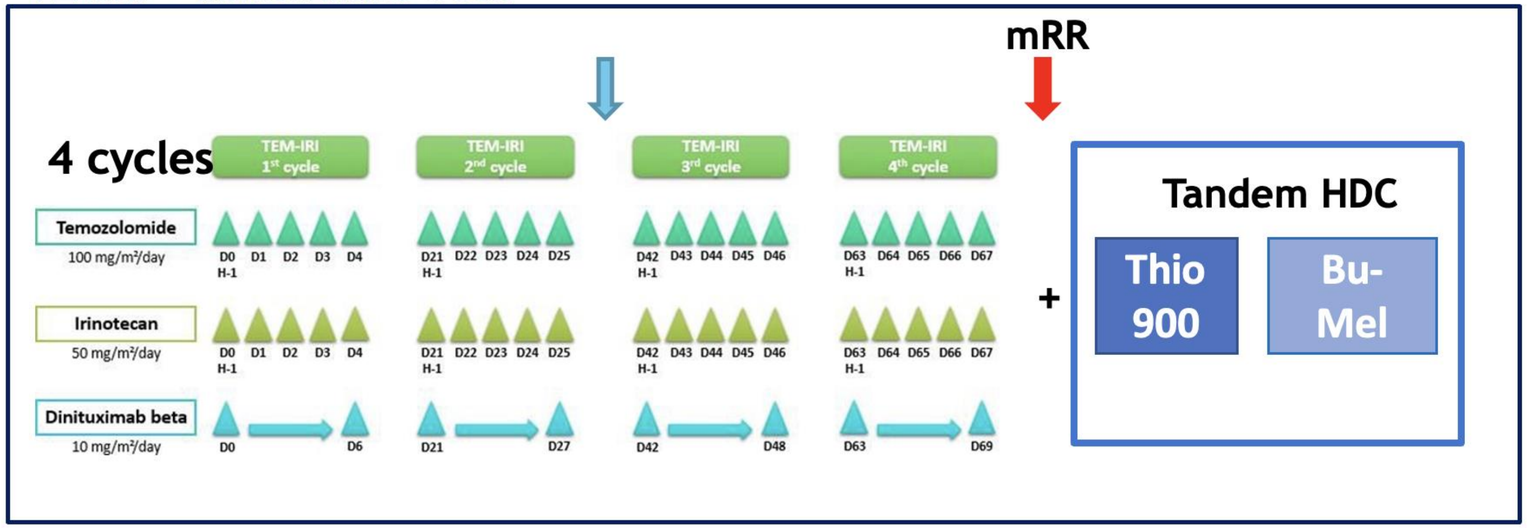
Moreno 2017

Chemio-immunoterapia nel neuroblastoma refrattario

NB-HR02 TRIAL



TEMIRI + dinutuximab beta



N = 93 pazienti previsti; 85 già arruolati
4 cicli di TEMIRI + dinutuximab beta
Successiva HDC tandem, salvo progressione
Endpoint primario: risposta metastatica dopo il ciclo 4

Naxitamab-based chemo-immunotherapy nei pazienti refrattari: lo studio HITS

Article

Early Salvage Chemo-Immunotherapy with Irinotecan, Temozolomide and Naxitamab Plus GM-CSF (HITS) for Patients with Primary Refractory High-Risk Neuroblastoma Provide the Best Chance for Long-Term Outcomes

Juan Pablo Muñoz, Cristina Larrosa, Saray Chamorro, Sara Perez-Jaume, Margarida Simao, Nazaret Sanchez-Sierra, Amalia Varo, Maite Gorostegui, Alicia Castañeda, Moira Garraus, Sandra Lopez-Miralles and Jaume Mora *

Irinotecan + temozolomide
Naxitamab anti-GD2
GM-CSF / sargramostim
Trattamento somministrato ogni 4 settimane in regime ambulatoriale

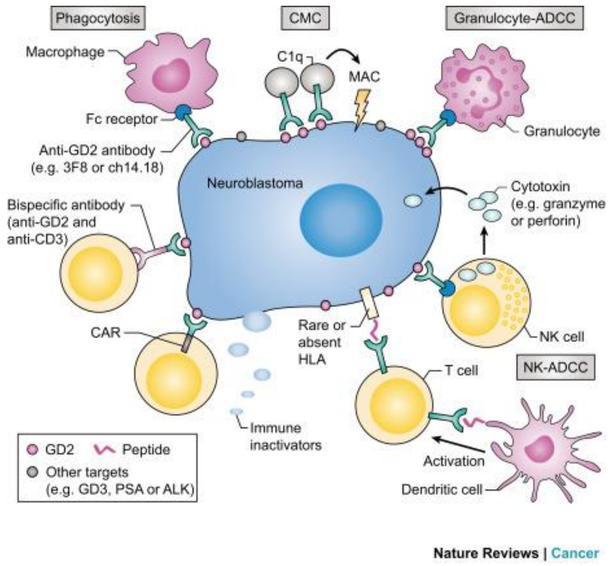
34 pazienti
Mediana di **4 cicli** di trattamento
Due coorti:

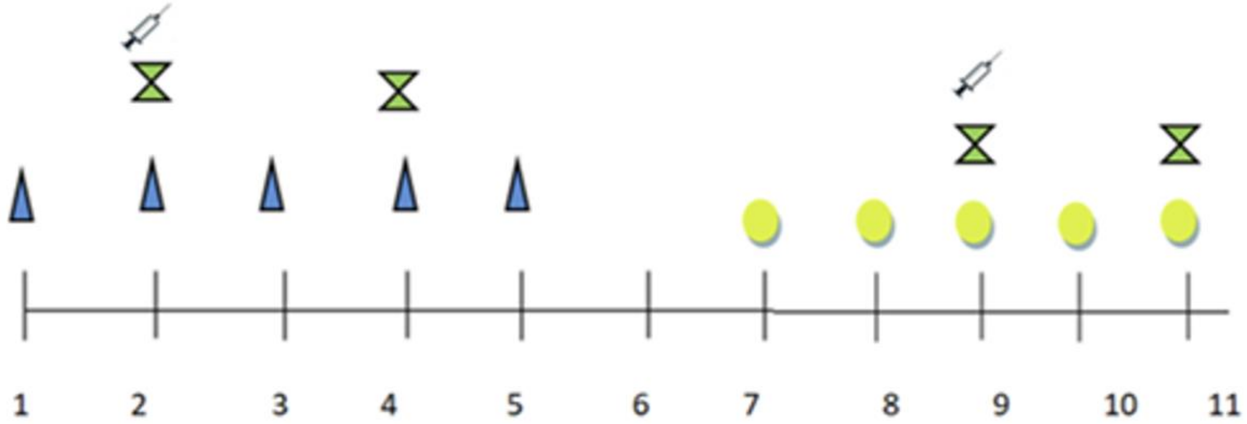
- **Early HITS**: subito dopo fallimento dell'induzione
- **Late HITS**: dopo ulteriori trattamenti di salvataggio

Munoz et al., Cancers, 2026

Che cos'è naxitamab?

- Anticorpo monoclonale umanizzato diretto contro **GD2**
- Impiegato nel neuroblastoma ad alto rischio **recidivato/refrattario** o in RC
- Il target GD2 è espresso sulla superficie delle cellule neuroblastiche
- L'attività antitumorale è potenziata dall'attivazione immunitaria con **GM-CSF**
- Somministrabile secondo schemi ripetuti, anche in **regime ambulatoriale**
- Cicli di trattamento ogni **21 giorni**





emozolamide + Irinotecan | Naxitamab | GM-CSF 250 ug/m² | controllo ematologico

Giorni	Trattamento
1–5	Irinotecan 50 mg/m²/die EV + Temozolomide 150 mg/m²/die PO
2, 4, 8, 10	Naxitamab 2.25 mg/kg EV
6–10	GM-CSF 250 mg/m²/die SC

NO con
GB >50000/mmc e/o
N >20000/mmc

Dose totale naxitamab/ciclo: 9 mg/kg,
equivalente a 270 mg/m²

Quali farmaci in associazione?

PREMEDICAZIONE (30 min prima del Naxitamab)		
FARMACO	**DOSE**	**VIA DI SOMMINISTRAZIONE**
Paracetamolo	15 mg/kg	Orale
Cetirizina	<20kg: 2.5 mg >20kg: 5 mg <30 kg e >12 anni: 10 mg	Orale
Famotidina	0.5 mg/kg	Orale
Gabapentin	**Iniziando la settimana precedente:** **10 mg/kg/dose** 1° giorno ogni 24h 2° giorno ogni 12h A partire dal 3° giorno ogni 8h	Orale
Ondansetron	0.15 mg/kg	Endovenosa
Analgesia	Secondo protocollo	Endovenosa
Metilprednisolone	1-2 mg/kg	Endovenosa **(1h prima del ciclo1)**

FARMACI AL BISOGNO DURANTE L'INFUSIONE			
FARMACO		**DOSE**	**VIA DI SOMMINISTRAZIONE**
Dexclorfeniramina		0.15 mg/kg	Endovenosa
Adrenalina		0.01 mg/kg	Intramuscolare
Adrenalina		5 mg	Aerosol
Salbutamolo		<20 kg: 2.5 mg >20 kg: 5 mg	Aerosol
Boli de SF		10-20 ml/kg	Endovenosa
"Combo"	**Midazolam**	0,25 mg-1 mg	Endovenosa
	Atropina	0,005-0,01 mg/kg/dose	
	Lidocaina	1-2 mg/kg	
	Ketamina	0,5-1 mg/kg dose	
Flumazeni		10 ug/kg/dose	Endovenosa
Naloxone		0.01 mg /kg	Endovenosa
FARMACI AL BISOGNO POST INFUSIONE			
Metamizolo o ketoprofene 1mg/kg se dolore residuo lieve **Morfina 50 ug/kg se dolore intenso**			

STEPPING UP

Pazienti

- 91 in totali
- 1° pz nel 2021 (<2 aa)

Dolore

- Più controllato
- Meno incidenza di dolore G3 (dose massima di ketamina 4m g/kg)

Analgesia

- Diminuzione dell'uso di morfina

Controllo successivo

- Miglior gestione del dolore residuo
- Miglior gestione a domicilio

Stati d'animo

- Diminuzione della preoccupazione e della paura del paziente e della famiglia

Somministazione a velocità crescente

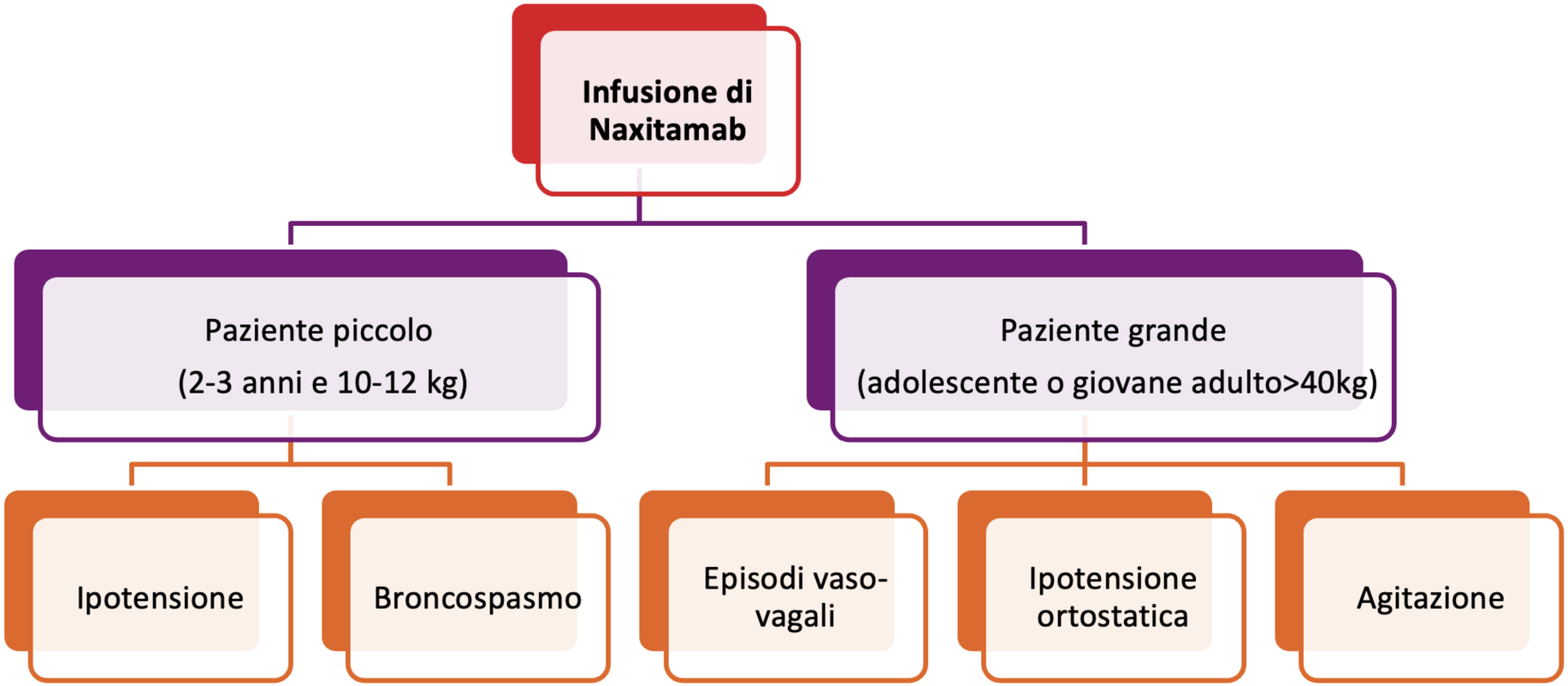
Durata circa 90-120 min

Evitare effetti avversi gravi

Somministrazione di Ketamina per il controllo del dolore

Courtesy of HSJD

EFFETTI SECONDARI IN CORSO DI INFUSIONE



EFFETTI SECONDARI ALLA DIMISSIONE

Osservazione di 2 ore prima della dimissione

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO OPEN | CANCER HORIZONS

REVIEW

How we approach the treatment of patients with high-risk neuroblastoma with naxitamab: experience from the Hospital Sant Joan de Déu in Barcelona, Spain

A. Castañeda, M. Gorostegui, S. L. Miralles, A. Chamizo, S. C. Patiño, M. A. Flores, M. Garraus, J. J. Lazaro, V. Santa-Maria, A. Varo, J. P. Muñoz & J. Mora*

Sant Joan de Déu Barcelona Children's Hospital, Barcelona, Spain

Available online xxx

Naxitamab [humanized 3f8 (hu3F8)] is a humanized monoclonal antibody (mAb) targeting the disialoganglioside GD2. It was approved in 2020 by the United States Food and Drug Administration (FDA) in combination with granulocyte–macrophage colony-stimulating factor (GM-CSF) for treatment of pediatric and adult patients with relapsed/refractory high-risk neuroblastoma, limited to the bone or bone marrow (BM). The team at Sant Joan de Déu Children's Hospital in Barcelona, Spain, have been using naxitamab to treat neuroblastoma under clinical trial protocols [e.g. Trial 201, and hu3F8, irinotecan, temozolomide, and sargramostim (GM-CSF) (HITS) study] and compassionate use since 2017. The team has experience with two primary regimens: naxitamab with GM-CSF only, or naxitamab in combination with irinotecan, temozolomide, and GM-CSF (chemoimmunotherapy). This article aims to provide a practical overview of the team's experience with naxitamab to date, including preparing the treatment room and selecting the team. Adverse event management, including the use of ketamine to manage pain during anti-GD2 mAb infusions, is also discussed. We hope this will provide practical information for other health care providers considering offering this treatment.

Key words: neuroblastoma, naxitamab, GM-CSF, high-risk, anti-GD2 immunotherapy

frontiers | Frontiers in Oncology

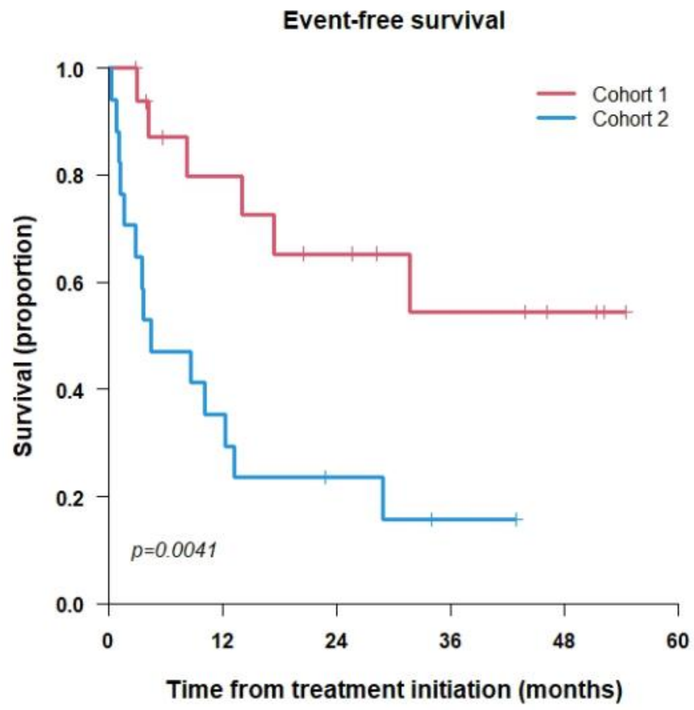
Desensitizing the autonomic nervous system to mitigate anti-GD2 monoclonal antibody side effects

Jaume Mora[1*], Alejandra Climent[2], Mònica Roldán[3], Marta Cecilia Flores[2], Amalia Varo[1], Sara Perez-Jaume[1], Cristina Jou[4], Mónica S. Celma[5], Juan José Lazaro[6], Irene Cheung[7], Alicia Castañeda[1], Maite Gorostegui[1], Eva Rodriguez[4], Saray Chamorro[1], Juan Pablo Muñoz[1] and Nai-Kong Cheung[7*]

[1]Pediatric Cancer Center Barcelona (PCCB), Hospital Sant Joan de Déu, Barcelona, Spain, [2]Department of Neurophysiology, Hospital Sant Joan de Déu, Barcelona, Spain, [3]Department of Genetics, Hospital Sant Joan de Déu, Barcelona, Spain, [4]Department of Pathology, Hospital Sant Joan de Déu, Barcelona, Spain, [5]Department of Pharmacy, Hospital Sant Joan de Déu, Barcelona, Spain, [6]Department of Anesthesiology, Hospital Sant Joan de Déu, Barcelona, Spain, [7]Department of Pediatrics, Memorial Sloan-Kettering Cancer Center (MSK), New York, NY, United States

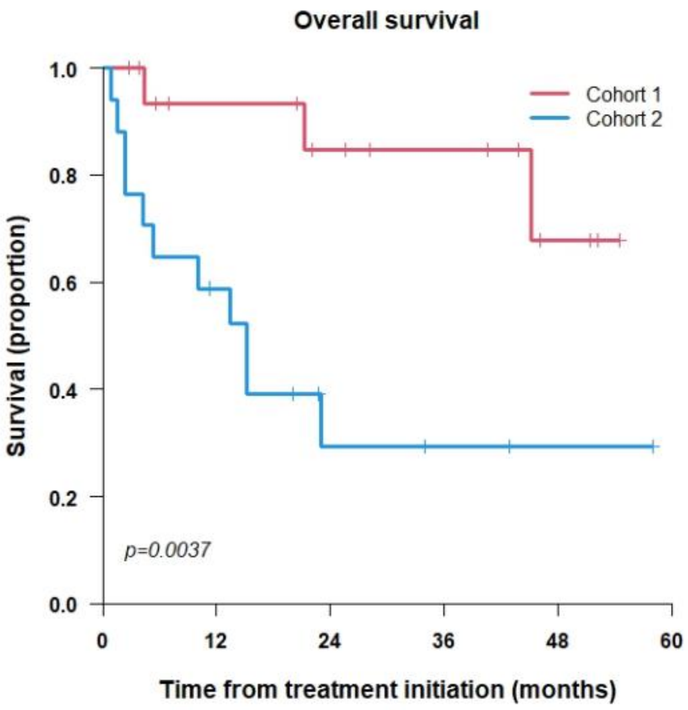
Background: Anti-GD2 monoclonal antibodies (mAbs) have shown to improve the overall survival of patients with high-risk neuroblastoma (HR-NB). Serious adverse events (AEs), including pain, within hours of antibody infusion, have limited the development of these therapies. In this study, we provide evidence of Autonomic Nervous System (ANS) activation as the mechanism to explain the main side effects of anti-GD2 mAbs.

CONTROLLO DI MALATTIA NEI NEUROBLASTOMA (NB) REFRATTARI E RECIDIVATI (RR): UNA QUESTIONE APERTA



N at risk

Cohort 1	17	11	8	5	3	0
Cohort 2	17	6	3	1	0	0



N at risk

Cohort 1	17	12	9	7	3	0
Cohort 2	17	9	3	2	1	0

- CR: **29%**
- **Early HITS:** CR **47%**
- **Late HITS:** CR **12%**
- Nessuna PD durante trattamento in coorte Early HITS

- **Early HITS:** OS a 3 anni **84,8%**, EFS **54,4%**
- **Late HITS:** OS a 3 anni **29,4%**, EFS **15,7%**
- Differenza significativa per OS ed EFS tra trattamento precoce e tardivo

- Tossicità attese: mielosoppressione/diarrea da I/T; dolore e alterazioni pressorie da naxitamab
- Tossicità ≥ G3 nel **85%** dei pz
- Nessuna tossicità di grado 5

Munoz et al., Cancers, 2026

Real-life Use of IV Naxitamab for Children With Relapsed/Refractory Neuroblastoma

Fried, Iris MD*; Weintraub, Michael MD*; Waldman, Dalia MD†; Revel-Vilk, Shoshana MD, PhD*

102 infusioni di naxitamab valutate
Protocollo analgesico semplificato: **solo ketamina** durante l'infusione
Dolore controllato in tutti i casi
AE grado 3–4: 10% delle infusioni
Nessuna interruzione per AE correlati all'infusione
AE significativi rari dopo il 3° ciclo

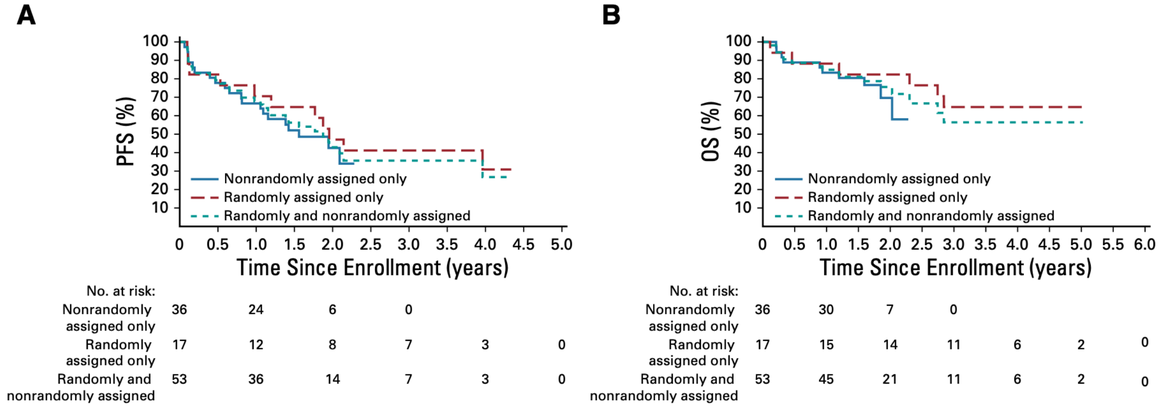
Fried et al., J. Pediatr. Hematol. Oncol, 2025

Chemio-immunoterapia nel neuroblastoma recidivato

JCO, 2020

Irinotecan, Temozolomide, and Dinutuximab With GM-CSF in Children With Refractory or Relapsed Neuroblastoma: A Report From the Children's Oncology Group

Rajen Mody, MS, MD[1]; Alice L. Yu, MD, PhD[2,3]; Arlene Naranjo, PhD[4]; Fan F. Zhang, MS[5]; Wendy B. London, PhD[6]; Barry L. Shulkin, MBA, MD[7]; Marguerite T. Parisi, MS, MD[8]; Sabah-E-Noor Servaes, MD[9]; Mitchell B. Diccianni, PhD[2]; Jacquelyn A. Hank, PhD[10]; Mildred Felder, BS[10]; Jennifer Birstler, MS[10]; Paul M. Sondel, MD, PhD[10]; Shahab Asgharzadeh, MD[11]; Julia Glade-Bender, MD[12]; Howard Katzenstein, MD[13]; John M. Maris, MD[9]; Julie R. Park, MD[8]; and Rochelle Bagatell, MD[9]



53 casi
Risposta obiettiva: 41,5%
Malattia stabile: 41,5%
PFS a 1 anno: 67,9%; OS a 1 anno: 84,9%

Frontiers in Oncology, 2022

Dinutuximab beta plus conventional chemotherapy for relapsed/refractory high-risk neuroblastoma: A single-center experience

Nur Olgun[1*], Emre Cecen[1], Dilek Ince[1], Deniz Kizmazoglu[1], Birsen Baysal[1], Ayse Onal[1], Ozhan Ozdogan[2], Handan Guleryuz[3], Riza Cetingoz[4], Ayse Demiral[4], Mustafa Olguner[5], Ahmet Celik[6], Serra Kamer[7], Erdener Ozer[8], Zekiye Altun[9] and Safiye Aktas[9]

19 casi

Frontiers in Oncology, 2023

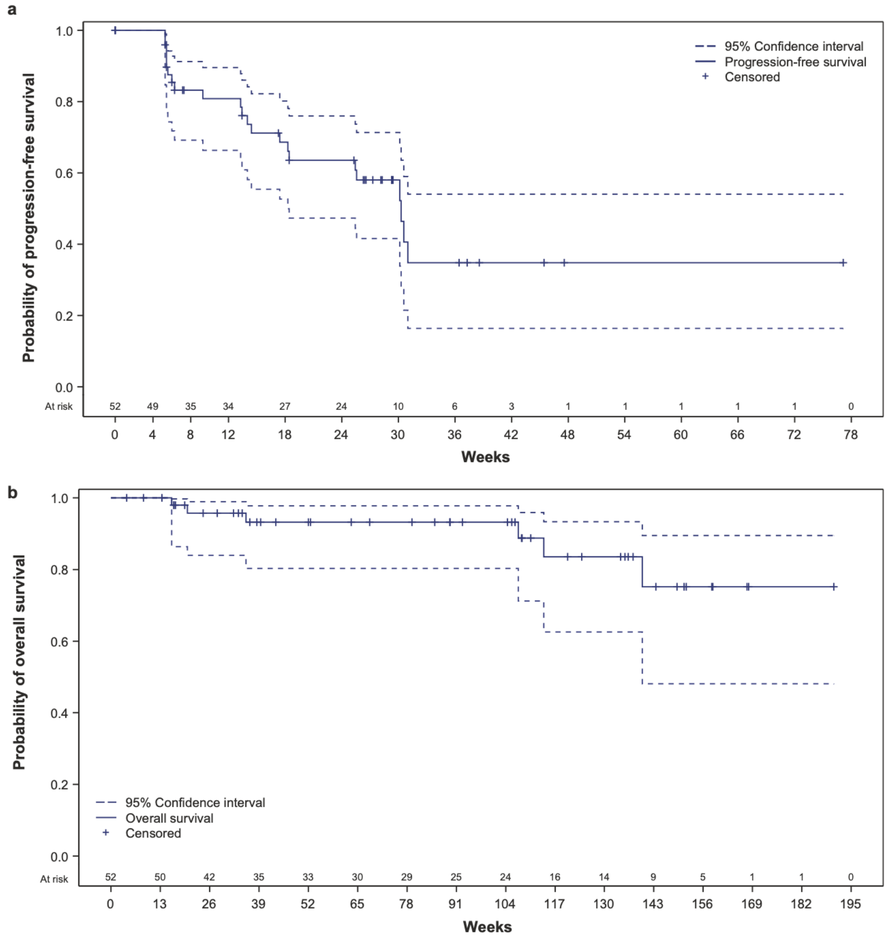
Dinutuximab beta combined with chemotherapy in patients with relapsed or refractory neuroblastoma

Aleksandra Wieczorek[1,2*], Anna Zaniewska-Tekieli[2], Karoline Ehlert[3], Katarzyna Pawinska-Wasikowska[1,2], Walentyna Balwierz[1,2†] and Holger Lode[3†]

25 casi

The anti-GD2 monoclonal antibody naxitamab plus GM-CSF for relapsed or refractory high-risk neuroblastoma: a phase 2 clinical trial

Studio fase 2, single-arm, non randomizzato
74 pazienti → 52 valutabili per efficacia
Popolazione: neuroblastoma R/R con **malattia residua in osso/BM**
Trattamento: naxitamab + GM-CSF ogni 4 settimane
ORR: 50%; CR: 38%; PR: 12%
Risposta compartimento osseo: 58%; midollare: 74%
OS a 1 anno: 93%
PFS a 1 anno: 35%
Tossicità G3 più frequenti: ipotensione e dolore
Conclusione: efficace e gestibile in setting ambulatoriale selezionato



Mora et al., Nature Comm., 2025

Systematic Review

Assessment of Chemo-Immunotherapy Regimens in Patients with Refractory or Relapsed Neuroblastoma: A Systematic Review with Meta-Analysis of Critical Oncological Outcomes

Nur Olgun [1,2,*], Mehmet Emin Arayici [3,4], Deniz Kızmazoglu [1] and Refik Emre Cecen [1]

Revisione sistematica e meta-analisi: 8 studi, 376 pazienti
Popolazione: neuroblastoma refrattario o recidivato
Regimi: dinutuximab/dinutuximab beta/naxitamab + chemioterapia
ORR pooled: 45%
OS pooled: 75%
EFS pooled: 59%
Limite: elevata eterogeneità e bias negli studi non randomizzati
Conclusione: approccio promettente, ma servono studi prospettici standardizzati e biomarcatori predittivi

Olgun et al., J. Clin. Med., 2025

Dinutuximab Beta Added to Temozolomide-Based Chemotherapy for Children With Relapsed and Refractory Neuroblastoma: Results of the ITCC-SIOPEN BEACON Immuno Phase II Trial

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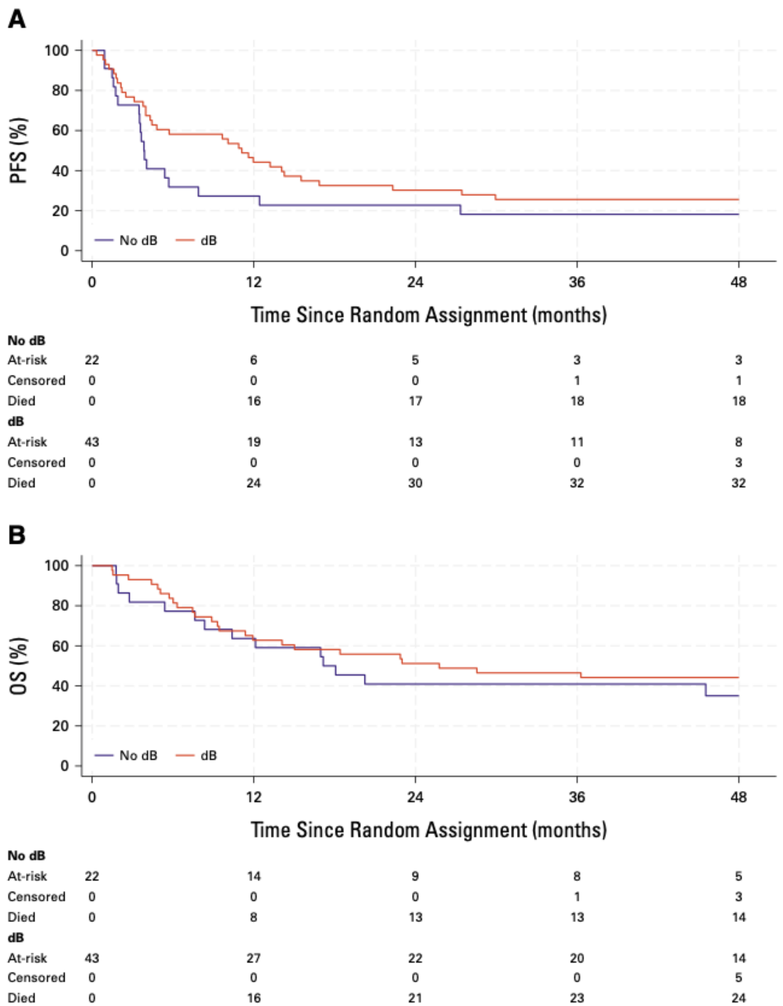

Trial fase II randomizzato: 65 pazienti RR-HR-NBL
Confronto: CT temozolomide-based ± dinutuximab-beta
ORR: 30,2% con dB vs 18,2% senza dB
PFS mediana: 11,1 vs 3,8 mesi
OS mediana: 25,7 vs 17,1 mesi, ma interpretazione limitata dal crossover
Tossicità: profilo accettabile; neurotossicità più frequente con dB, dolore generalmente ben controllato

Gray et al., JCO, 2026

A Phase II Trial of Naxitamab plus Stepped-up Dosing of GM-CSF for Patients with High-Risk Neuroblastoma in First Complete Remission

Brian H Kushner [1], Shakeel Modak [1], Audrey Mauguen [2], Ellen M Basu [1], Kim Kramer [1], Stephen S Roberts [1], Irene Y Cheung [1], Nai-Kong V Cheung [1]

Studio fase II su 59 pazienti HR-NB in prima CR
Trattamento: naxitamab + GM-CSF + isotretinoina
Somministrazione ambulatoriale mensile, fino a 5 cicli
EFS a 36 mesi: 73%; OS a 36 mesi: 93%
6/18 recidive isolate nel SNC
Trattamento tollerabile, anche in pazienti senza ASCT

Kushner et al., Clin. Cander Res., 2025

A phase II trial of naxitamab plus stepped-up dosing of GM-CSF for patients with high-risk neuroblastoma in second or later complete remission

Brian H Kushner [1], Shakeel Modak [1], Charlie White [2], Ellen M Basu [1], Stephen S Roberts [1 3], Audrey Mauguen [2], Nai-Kong V Cheung [1]

Studio fase II su 60 pazienti in seconda o successiva CR
Trattamento: naxitamab + GM-CSF per 5 cicli mensili
42 pazienti dopo 1 recidiva; 18 dopo ≥2 recidive
MYCN amplificato nel 45%
PFS: 55% a 2 anni; 50% a 5 anni
Fattori prognostici negativi: precedente naxitamab e recidiva diffusa
Limite: outcome influenzato da terapie post-protocollo

Kushner et al., Int J Cancer, 2026

High-risk neuroblastoma in Mexico: from multimodal treatment to immunotherapy. Regarding the first case treated with naxitamab

Alberto Olaya Vargas [1], Haydee Salazar-Rosales [1], Marcela Caballero-Palacios [2], Nideshda Ramírez-Uribe [1], Gerardo López-Hernández [1], Erika Morales-Martinez [1], María Cervantes-Delgado [1], Liliana Velasco Hidalgo [2], Araceli Castellanos-Toledo [2], Rocío Cárdenas-Cardos [2 3], Ana Niembro-Zúñiga [2], Roberto Rivera-Luna [2], Alberto Olaya-Nieto [1], Jesús Ponce-Cruz [3], Jaime Shalkow-Klincovstein [3], Yadira Melchor-Vidal [3], Rodrigo Díaz-Machorro [3]

Discussion: The primary objective of implementing novel immunotherapeutic strategies, in addition to improving event-free survival (EFS) and overall survival (OS) in patients diagnosed with high-risk neuroblastoma, is to reduce adverse effects and lower both short- and long-term mortality. It is worth noting that the current cost of anti-GD2 therapies available in Latin America is estimated to exceed $450,000 USD. In a country like Mexico, where the minimum daily wage is approximately $10 USD, access to these therapies remains unattainable for the majority of the population. Therefore, it is essential to highlight the importance and substantial clinical impact of immunotherapy on survival outcomes in patients with refractory neuroblastoma. This recognition should support advocacy for broader access to these therapies. Despite their high costs, the demonstrated benefits should outweigh the disadvantages, justifying efforts to make them accessible to all patient populations.

Vargas et al., Front Oncol.., 2025

CONCLUSIONI

La chemio-immunoterapia anti-GD2 sta cambiando il paradigma terapeutico del neuroblastoma HR recidivato/refrattario

- Evidenza crescente di attività clinica in studi prospettici, retrospettivi e real-world
- Il **timing precoce** sembra cruciale: migliori risultati prima di multiple linee di salvataggio
- Maggiore efficacia nei compartimenti **osso/midollo**, mentre soft tissue e SNC restano sfide aperte
- La **gestione del dolore e delle reazioni infusionali** è determinante per fattibilità e trattamento ambulatoriale
- Servono studi randomizzati, biomarcatori predittivi e strategie di consolidamento più mirate

Take-home message

L'anti-GD2 non è solo un farmaco aggiunto alla chemioterapia, ma una piattaforma terapeutica da integrare nel paziente giusto, al momento giusto, con una gestione tossicologica strutturata

Grazie!

Un sincero grazie alle famiglie, ai colleghi e a tutto il team multidisciplinare.

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