Plány CMG pro období 2005-2006

R. Hájek

Čejkovice 2.4.2005

Seminář CMG pro nemocné s MM a jejich blízké

Iveta Mareschová
koordinátor

CZECH MYELOMA GROUP
ČESKÁ MYELOMOVÁ SKUPINA

Česká myelomová skupina spolupracuje s lékaři v ČR a SR při zajištění nových léků pro léčbu nemocných s mnohočetným myelomem

Hotel My Lednice

Lůžková kapacita: 94

Max. počet míst:

85 - restaurace

30 - salónek

150 - sál

Předběžný plán semináře

- **Kdy:** 2-3.9.2005 (pá,so)
- **Kde:** My Hotel, Lednice
- **Kapacita:** 100 - 130 účastníků
- **VIP host:** Susie Novis (IMF)
- **Rozpočet:** 452 tis. (předběžná kalkulace)
  - *ubytování - 100 tis.*
  - *stravování - 150 tis.*
  - *pronájem sálu a techniky - 32 tis.*
  - *doprava - 70 tis.*
  - *administrativa - 100 tis.*

Předběžná analýza dotazníků

	Počet	
Hodnocené dotazníky	90	
	ANO	NE
Zájem	64 (71%)	26 (29%)
Účast rodinných příslušníků	43 (48%)	13 (14%)
Konání mimo bydliště	26 (29%)	14 (40%)
Den konání	Po, Út, St, Čt	Pá, So, Ne
	22 (24%)	18 (20%)
Počet účastníků	Menší skupina	Nezáleží na počtu
	20 (22%)	37 (41%)
Opakování semináře	Není nutné	1x ročně
	10 (11%)	41 (45%)

V případě, že není zhodnoceno 100%, údaje nebyly vyplněny

Předběžný návrh programu

- Pátek - příjezd v odpoledních hodinách (jen kdo má zájem přenocovat)
  - večerní nezávazné posezení
- Sobota - hlavní program
  - dopolední blok 9,00 - 13,00 hod. (1x přestávka)
  - oběd
  - odpolední blok 14,00 - 16,30 hod. (1x přestávka)

Předběžný návrh programu

- Sobota - hlavní program

Dopolední

- Diagnostika a příznaky mnohočetného myelomu
- Standardní léčba
- Vysokodávkovaná chemoterapie a autologní transplantace kmenových krvetvorných buněk
- Novinky v léčbě
- Vertebroplastika - nový léčebný přístup

Odpolední

- Rozdělení do skupin - diskuse s lékaři

(standardní a transplantační léčba, novinky, péče o rodinné příslušníky)

Děkuji za pozornost

Klinická studie CMG 2006

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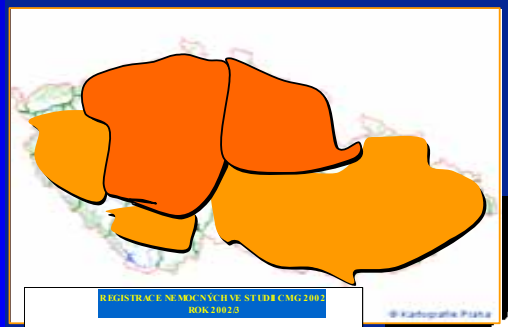
SROVNÁNÍ STUDIE 4W & CMG 2002

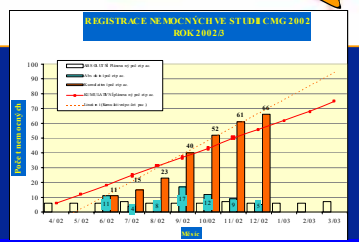
4W

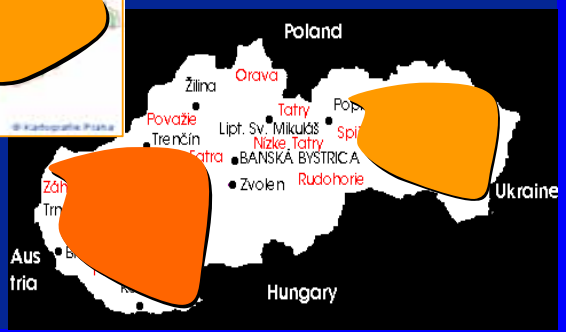
249 pts./ 6 years

SROVNÁNÍ STUDIE 4W & CMG 2002



CMG 2002





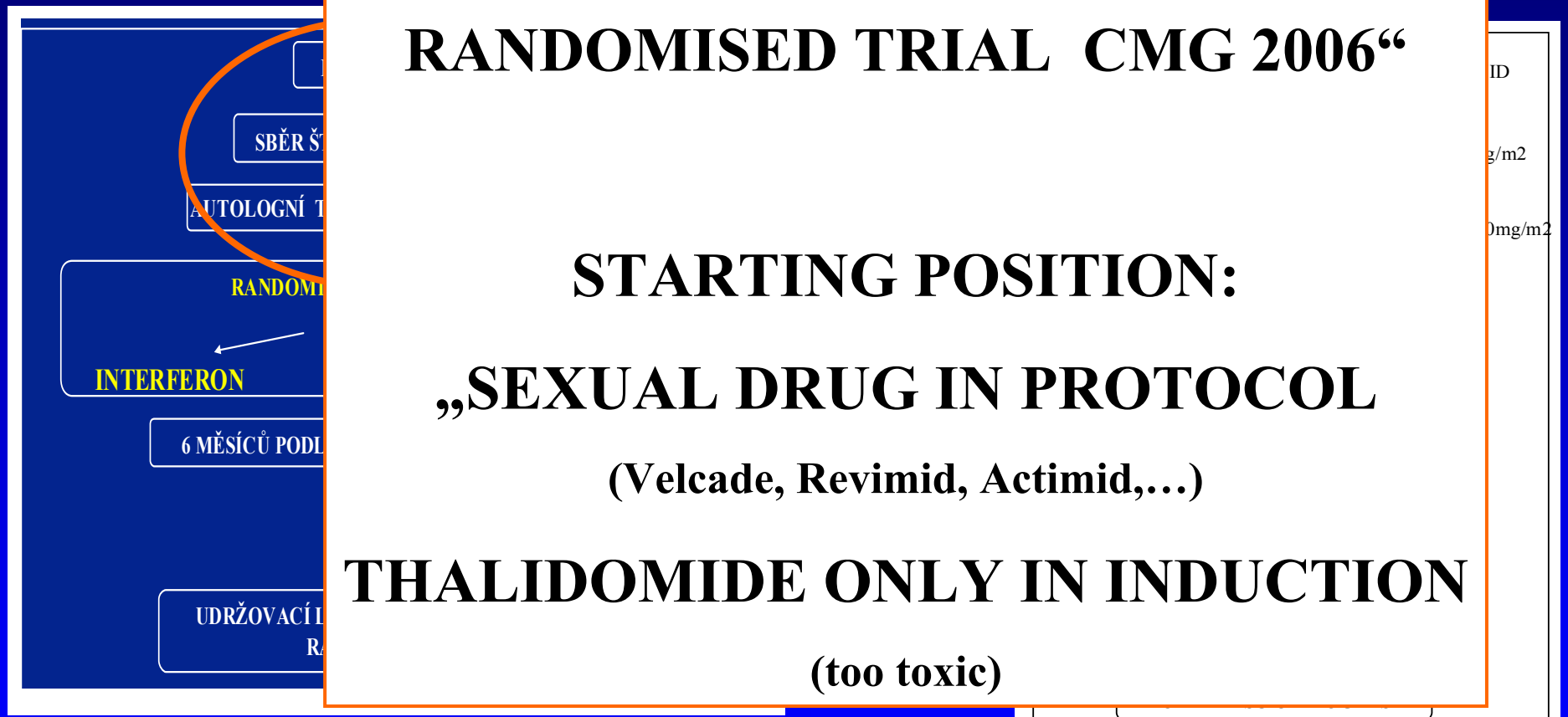
232 pts./ 2 years

Proposed Summary of the Trial CMG 2002 (September 2006)

- 520 pts. enrolled during 4 years
- 410 pts. underwent transplantation
- 400 randomised
- 25 cooperative centers in CR and SR
- 9 transplantation centers - Brno, Bratislava, Hradec Králové, Košice, Martin, Olomouc, Plzeň, Praha 2x,

Randomised trials of CMG

Klinické 2002



„FIRST CALL“

RANDOMISED TRIAL CMG 2006“

STARTING POSITION:

„SEXUAL DRUG IN PROTOCOL

(Velcade, Revimid, Actimid,…)

THALIDOMIDE ONLY IN INDUCTION

(too toxic)

CZECH MYELOMA GROUP
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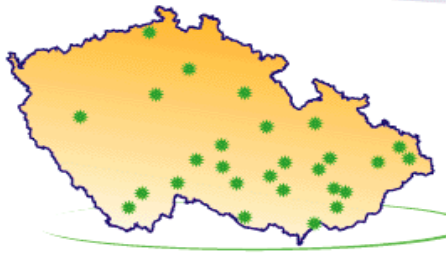
Czech Myeloma Group

Organisation for research and treatment of multiple myeloma

CZECH MYELOMA GROUP

- **Research centers**
  CMG coordinates research activities of 32 centers in Czech Republic and 2 in Slovak Republic.



Organisation

Logistic background

Monitoring and GCP

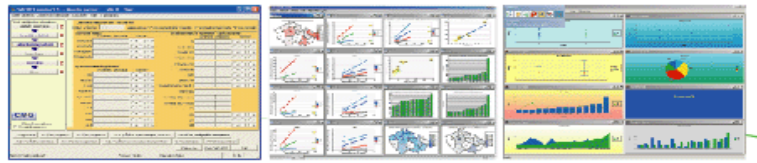
Centre of Biostatistics and Analyses

Research organization providing broad spectrum of services in the field of medicine informatics and clinical trials

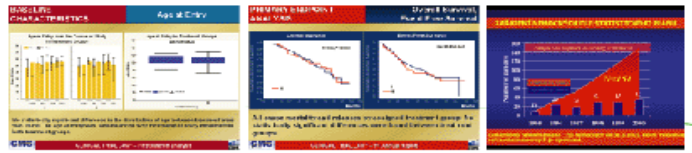
CENTRE OF BIOSTATISTICS AND ANALYSES, MASARYK UNIVERSITY BRNO

- **Protocol development**
  CBA provides complete services in protocol development in accordance with ICH GCP principles.

- **Software development**
  CBA develops software products for data entry and statistical analyses of clinical trials.



- **Data analysis and interim analyses**
  CBA provides complete statistical servises in the field of clinical trials data analyses.



- **Pharmacovigilance**
  CBA provides complete services in adverse events reporting (regulatory authorities and pharmaceuticals compmanies).

Contacts:

To obtain more information about CBA or to start any form of collaboration please contact

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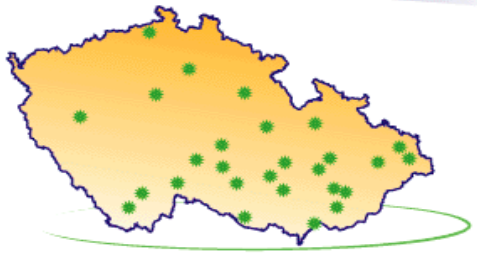

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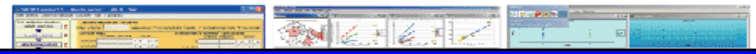

New EU Legislative for GCP and Clinical Trial

New „Monitoring Team“ for CMG Trials Supported by CMG Foundation

Standardization of key methods and samples collections is in process

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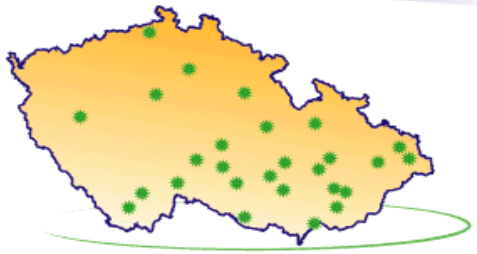

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CBA service = high standard

including proccesses of:

registration and randomization

annual reports

statistic and analyses

trial planning and preparation

sofware-databases (on line)

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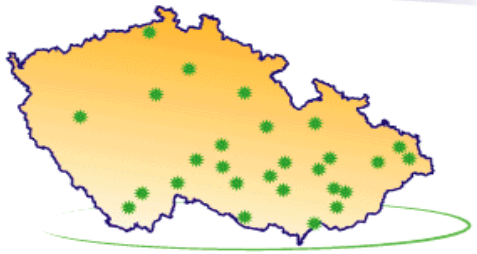

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CMG is well established group but with limited potential for enrollment of optimal number of pts. during 4 years.

Cooperation

Internationalisation

More publications

FIRST STEP

How many patients we are able to enroll to the trial during 4 years.

EPIDEMIOLOGIC DATA
&
NUMBER OF PTS. AVAILABLE TO THE TRANSPLANT TRIALS

Country	*Number of Cases*	***Age reduction***
Czech Rep.	**550**	**250**
Slovakia	**275**	**130**
Austria	**400**	
Hungary	**400**	
Poland	**2 400**	

400-450 PTS./ 4 YEARs

???

SECOND STEP

Who will be a sponsor of the trial ?

THIRD STEP

Design of the protocol ?

Randomization arms:

2,3,…& Induction, MT, Consolidation,

Transplantation:

Transplantation 0, 1 or 2 ?

How to implement the new drugs to treatment schedule ?

How many pts. will be required, if median OS in current trial are already now prolonged up to 6 years ?

Crossover is main limit for OS evaluation btw. Two arms.

The main goals:

Strong cooperative group with potential of 800 pts./4 years

Newly designed protocol
sponzored by one of the key fy.
{Velcade or Revlimide or…}

Suitable protocol for patients, for economy,
as well as for doctors

Prosíme o spolupráci

a

Děkuji za pozornost